

# ABIRATERONE

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## Products Affected

- Abiraterone Acetate

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of metastatic castration-resistant prostate cancer (CRPC) OR metastatic high-risk castration-sensitive prostate cancer (CSPC). Abiraterone will be used in combination with prednisone. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

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Last Updated: June 2024

# ACTEMRA SC

## Products Affected

- Actemra INJ 162MG/0.9ML

- Actemra Actpen

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | <p>Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib) or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Giant Cell Arteritis (GCA) (Initial): Diagnosis of GCA. TF/C/I to a glucocorticoid (eg, prednisone). Systemic Juvenile Idiopathic Arthritis (SJIA) (Initial): Diagnosis of active SJIA. TF/C/I to one of the following conventional therapies at maximally tolerated doses: minimum duration of a one month trial of a nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen), minimum duration of a 3-month trial of methotrexate, or minimum duration of a 2-week trial of a systemic glucocorticoid (eg, prednisone). Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of active PJIA. One of the following: a) TF/C/I to two of the following, or attestation demonstrating a trial may be inappropriate: Enbrel (etanercept), Humira (adalimumab), Orencia (abatacept), or Xeljanz (tofacitinib), OR b) for continuation of prior therapy. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) (Initial): Diagnosis of SSc-ILD as documented by the following: a) Exclusion of other known causes of ILD AND b) One of the following: i) In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (eg, fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on high-resolution computed tomography (HRCT) revealing SSc-ILD or probable SSc-ILD, OR ii) In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD.</p> |
| Age Restrictions             | N/A  |

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|                                |  |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | RA, GC, SJIA, PJIA (initial): Prescribed by or in consultation with a rheumatologist. SSc-ILD (initial): Prescribed by or in consultation with a pulmonologist or rheumatologist.  |
| <b>Coverage Duration</b>       | Plan year  |
| <b>Other Criteria</b>          | RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. SJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in clinical features or symptoms (eg, pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline. GC, SSc-ILD (Reauth): Patient demonstrates positive clinical response to therapy. |

# ADEMPAS

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## Products Affected

- Adempas

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of pulmonary arterial hypertension (WHO group I) and diagnosis was confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.) OR Patient has a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH, WHO group 4) and patient has persistent or recurrent disease after surgical treatment (e.g., pulmonary endarterectomy) or has CTEPH that is inoperable. |
| <b>Age Restrictions</b>             | 18 years of age or older  |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | For renewal, medication was effective (i.e. improved 6 minute walk distance, oxygen saturation, etc.)   |

# AIMOVIG

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## Products Affected

- Aimovig

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of either episodic migraines or chronic migraines. For episodic migraine, patient must have both of the following: less than 15 headache days per month and 4-14 migraine days per month. For chronic migraine, patient must have both of the following: at least 15 headache days per month and at least 8 migraine days per month. Patient has had a trial and failure or contraindication to at least 2 different preventative migraine medications. |
| <b>Age Restrictions</b>             | 18 years of age or older  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a neurologist, pain specialist, or headache specialist  |
| <b>Coverage Duration</b>            | Initial: 3 months. Renewal: plan year.  |
| <b>Other Criteria</b>               | For renewal, patient must have a positive clinical response.  |

# AKEEGA

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## Products Affected

- Akeega

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC). And will be used in combination with prednisone. And will be used in combination with a gonadotropin-releasing hormone (GnRH) analog OR patient has had a bilateral orchiectomy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# ALECENSA

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## Products Affected

- Alecensa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of metastatic non-small cell lung cancer (NSCLC) with anaplastic lymphoma kinase (ALK) positive disease. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# ALPHA1 PROTEINASE INHIBITOR

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## Products Affected

- Aralast Np INJ 1000MG, 500MG
- Glassia
- Prolastin-c
- Zemaira

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of clinically evident emphysema and severe hereditary deficiency of alpha1-antitrypsin. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |



# ALUNBRIG

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## Products Affected

- Alunbrig

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# AMBRISENTAN

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## Products Affected

- Ambrisentan

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | Pregnancy   |
| <b>Required Medical Information</b> | Patient has a diagnosis of pulmonary arterial hypertension (WHO Group I). For female patients of childbearing potential: 1) Pregnancy was excluded prior to initiation of therapy, AND 2) Patient will use reliable contraception during treatment and for one month after stopping treatment |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# ARMODAFINIL

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## Products Affected

- Armodafinil

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis of excessive sleepiness associated with obstructive sleep apnea (OSA)/hypopnea syndrome and documentation of residual excessive sleepiness OR Diagnosis of excessive sleepiness associated with narcolepsy and patient has tried and failed, is unable to tolerate, or has contraindication(s) to at least one other central nervous system stimulant (e.g., methylphenidate, mixed amphetamine salts, dextroamphetamine) OR Diagnosis of excessive sleepiness associated with shift work disorder. |
| <b>Age Restrictions</b>             | 17 years of age or older  |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# AUBAGIO

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## Products Affected

- Aubagio
- Teriflunomide

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Severe hepatic impairment. Pregnancy. Concomitant use with leflunomide.  |
| <b>Required Medical Information</b> | Patient has a diagnosis of a relapsing form of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. Serum transaminase and bilirubin levels must be drawn within 6 months prior to initiation of therapy with teriflunomide. For female patients of childbearing potential: Pregnancy was excluded prior to initiation of therapy and patient will use reliable contraception during treatment. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# AUGTYRO

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## Products Affected

- Augtyro

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | Some FDA-approved Indications Only.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Dx of locally advanced or metastatic ROS1-positive non-small cell lung cancer in adults |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# AURYXIA

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## Products Affected

- Auryxia

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Auryxia will not be approved for a diagnosis of iron deficiency anemia.                              |
| <b>Required Medical Information</b> | Patient has a diagnosis of hyperphosphatemia. Patient has chronic kidney disease and is on dialysis. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# AUSTEDO

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## Products Affected

- Austedo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | Actively suicidal or has untreated or inadequately treated depression. Impaired hepatic function. Concomitant monoamine oxidase inhibitor (MAOI) or use within 14 days of stopping MAOI. Concomitant reserpine or use within 20 days of stopping reserpine. Concomitant tetrabenazine (Xenazine). |
| <b>Required Medical Information</b> | Patient has a diagnosis of chorea associated with Huntington's disease OR has a diagnosis of tardive dyskinesia clinically diagnosed with all of the following: involuntary athetoid or choreiform movements, history of treatment with dopamine receptor blocking agent.                         |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# AYVAKIT

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## Products Affected

- Ayvakit

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has unresectable or metastatic gastrointestinal stromal tumors (GIST) with a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. Patient has a diagnosis of advanced systemic mastocytosis including patients with aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm, and mast cell leukemia OR indolent systemic mastocytosis AND patient has a platelet count greater than 50,000/mm <sup>3</sup> . |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |



# BALVERSA

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## Products Affected

- Balversa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of locally advanced or metastatic urothelial carcinoma. The patient has susceptible FGFR3 or FGFR2 genetic alterations and has progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# BENLYSTA

## Products Affected

- Benlysta

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Severe active CNS lupus, or use of Benlysta in combination with other biologics, including B-cell targeted therapies or intravenous (IV) cyclophosphamide  |
| <b>Required Medical Information</b> | Patient has active, autoantibody-positive systemic lupus erythematosus (SLE) and is receiving standard therapy (corticosteroids, azathioprine, leflunomide, methotrexate, mycophenolate mofetil, hydroxychloroquine, non-steroidal anti-inflammatory drugs) or is not on standard therapy due to past trial and inadequate response or intolerance. Patient has a diagnosis of active lupus nephritis. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# BESREMI

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## Products Affected

- Besremi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>                       |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.                 |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of polycythemia vera. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year                                     |
| <b>Other Criteria</b>               | N/A   |

# BEXAROTENE

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## Products Affected

- Bexarotene CAPS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of cutaneous T-cell lymphoma and is refractory to at least 1 prior systemic therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# BOSENTAN

## Products Affected

- Bosentan

- Tracleer TBSO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Pregnancy. Concomitant use with cyclosporine or glyburide. For initial therapy: alanine aminotransferase (ALT)/aspartate aminotransferase (AST) level greater than 3 times the upper limit of normal (ULN).  |
| <b>Required Medical Information</b> | Diagnosis of pulmonary arterial hypertension (WHO Group I) that was confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.). NYHA Functional Class II to IV symptoms. For female patients of childbearing potential: 1) Pregnancy was excluded prior to initiation of therapy, and 2) Patient will use reliable contraception during treatment and for one month after stopping treatment |
| <b>Age Restrictions</b>             | Age 3 and older  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# BOSULIF

## Products Affected

- Bosulif

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of chronic (newly diagnosed or previously treated), accelerated, or blast phase Philadelphia chromosome-positive chronic myelogenous leukemia (CML). For a diagnosis of accelerated phase or blast phase, patient had resistance or intolerance to prior treatment. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# BPH VS ED

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## Products Affected

- Tadalafil TABS 2.5MG, 5MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Not covered for the treatment of Erectile Dysfunction. Maximum dose: 5mg daily |
| <b>Required Medical Information</b> | Patient must have a diagnosis of BPH.  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# BRAFTOVI

## Products Affected

- Braftovi CAPS 75MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For a diagnosis of unresectable or metastatic melanoma: patient has a BRAF V600E or V600K mutation, will be used in combination with binimetinib (Mektovi), patient was not previously treated with a BRAF inhibitor or MEK inhibitor. For a diagnosis of metastatic colorectal cancer: patient has a BRAF V600E mutation, will be used in combination with cetuximab, patient has been on prior therapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |



# BRUKINSA

## Products Affected

- Brukinsa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of mantle cell lymphoma and has received at least 1 prior therapy. Patient has a diagnosis of Waldenström's macroglobulinemia (WM). Patient has a diagnosis of relapsed or refractory marginal zone lymphoma (MZL) and has received at least one anti-CD20-based regimen. Patient has a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# CABOMETYX

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## Products Affected

- Cabometyx

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of advanced renal cell carcinoma (RCC) and meets one of the following: will be used as monotherapy OR will be used in combination with nivolumab for first-line treatment. Patient has a diagnosis of advanced hepatocellular carcinoma and has been previously treated with sorafenib. Patient has a diagnosis of differentiated thyroid cancer that is locally advanced or metastatic and has progressed following prior VEGFR- targeted therapy and is radioactive iodine-refractory or ineligible. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# CALQUENCE

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## Products Affected

- Calquence

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of mantle cell lymphoma and has had at least 1 prior treatment, chronic lymphocytic leukemia (CLL), or small lymphocytic lymphoma (SLL). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# CAPRELSA

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## Products Affected

- Caprelsa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Patient has congenital long QT syndrome.   |
| <b>Required Medical Information</b> | Patient has a diagnosis of symptomatic or progressive medullary thyroid cancer. Patient has unresectable locally advanced or metastatic disease. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# CHOLBAM

## Products Affected

- Cholbam

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of a bile acid synthesis disorder due to single enzyme defects (SEDs) OR Cholbam is being used as an adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients with manifestations of liver disease, steatorrhea or complications from decreased fat soluble vitamin absorption. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by a hepatologist or gastroenterologist.   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# CINRYZE

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## Products Affected

- Cinryze

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of hereditary angioedema.  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an allergist or immunologist or another physician that specializes in the treatment of hereditary angioedema |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# COMETRIQ

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## Products Affected

- Cometriq

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of progressive, metastatic, medullary thyroid cancer. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# COPIKTRA

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## Products Affected

- Copiktra

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of chronic lymphocytic leukemia or small lymphocytic lymphoma. Patient has had at least two prior therapies. Prophylaxis for <i>Pneumocystis jirovecii</i> (PJP) will be provided during treatment. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |



# COSENTYX

## Products Affected

- Cosentyx
- Cosentyx Sensoready Pen
- Cosentyx Unoready

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | <p>Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month trial and failure, contraindication, or intolerance to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. Non-radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of active nr-axSpA with objective signs of inflammation (eg, C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) Enthesitis-Related Arthritis (ERA) (Initial): Diagnosis of active ERA. nr-axSpA, ERA (Initial): Minimum duration of a one-month TF/C/I to two non-steroidal anti-inflammatory drugs (NSAIDs) (eg, ibuprofen, naproxen) at maximally tolerated doses.</p> |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | <p>Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a rheumatologist or dermatologist. AS, nr-axSpA, ERA (initial): Prescribed by or in consultation with a rheumatologist.</p>   |

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|                          |  |
|--------------------------|--|
| <b>Coverage Duration</b> | Plan year  |
| <b>Other Criteria</b>    | <p>PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS, nr-axSpA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. ERA (Reauth): Patient demonstrates a positive clinical response to therapy as evidenced by at least one of the following: Reduction in the total active (swollen and tender) joint count from baseline, OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline.</p> |

# COTELLIC

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## Products Affected

- Cotellic

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of unresectable or metastatic melanoma. Patient has a BRAF V600E or V600K mutation. Cobimetinib will be used in combination with vemurafenib (Zelboraf). Patient has a diagnosis of histiocytic neoplasms. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# CYLTEZO

## Products Affected

- Cyltezo

- Cyltezo Starter Package For Crohns Disease/uc/hs INJ 40MG/0.8ML
- Cyltezo Starter Package For Psoriasis

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | <p>Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. PsO (Initial): Diagnosis of moderate to severe chronic PsO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week TF/C/I to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), methotrexate. Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis.</p> |

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|                                |   |
|--------------------------------|---|
| <b>Age Restrictions</b>        | N/A   |
| <b>Prescriber Restrictions</b> | RA, AS, PJIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS (initial): Prescribed by or in consultation with a dermatologist. CD, UC (initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist. |
| <b>Coverage Duration</b>       | Plan Year   |

|                              |   |
|------------------------------|---|
| <p><b>Other Criteria</b></p> | <p>Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), aminosalicylate [eg, mesalamine, olsalazine, sulfasalazine]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Hidradenitis suppurativa (HS), Uveitis (Reauth): Patient demonstrates positive clinical response to therapy. Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. CD (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. UC (Reauth): For patients who initiated therapy within the past 12 weeks: Patient demonstrates clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on therapy for longer than 12 weeks: Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.</p> |
|------------------------------|---|

# DALFAMPRIDINE

## Products Affected

- Dalfampridine Er

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Moderate to severe renal impairment (CrCL less than or equal to 50 mL/min) and/or history of seizures.   |
| <b>Required Medical Information</b> | Patient must have the ability to walk 25 feet (with or without assistance) prior to starting dalfampridine. Patient has a diagnosis of multiple sclerosis.   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | To continue therapy, the patient must experience improvement in walking speed or other objective measure of walking ability since starting dalfampridine. Dalfampridine at doses exceeding 10mg twice daily are not covered. |

# DAURISMO

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## Products Affected

- Daurismo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of acute myeloid leukemia (AML) and is newly diagnosed. Daurismo (glasdegib) will be used in combination with low-dose cytarabine. Patient is 75 years old or older OR has comorbidities that precludes the use of intensive induction chemotherapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |



# DEFERASIROX

## Products Affected

- Deferasirox

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | Patients with an eGFR less than 40mL/min/1.73m <sup>2</sup> . Patient's with a platelet count less than 50 million/L.   |
| <b>Required Medical Information</b> | (1) For chronic iron overload due to blood transfusions, Diagnosis of chronic iron overload due to blood transfusions and current serum ferritin level greater than 1000 mcg/L. (2) For iron overload in patients with NON-transfusion-dependent thalassemia (NTDT), a) Diagnosis of a NON-transfusion thalassemia syndrome and chronic iron overload, b)For initiation: i) pretreatment LIC of at least 5 mg per gram of dry weight and ii) pretreatment serum ferritin levels greater than 300 mcg/L and iii) For patients currently on deferasirox therapy: current LIC is greater than 3 mg per gram of dry weight or deferasirox will be withheld until the LIC reaches above 5 mg per gram of dry weight. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# DEFERIPRONE

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## Products Affected

- Deferiprone
- Ferriprox SOLN
- Ferriprox Twice-a-day

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of transfusion-related iron overload due to thalassemia syndromes or a diagnosis of sickle cell anemia or other anemias. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# DIACOMIT

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## Products Affected

- Diacomit

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of seizures associated with Dravet syndrome.<br>Patient will be on stiripentol with clobazam. |
| <b>Age Restrictions</b>             | Patient is 6 months of age or older.  |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# DICLOFENAC

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## Products Affected

- Diclofenac Sodium GEL 3%

| <b>PA Criteria</b>                  | <b>Criteria Details</b>                             |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.                       |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient must have a diagnosis of actinic keratosis. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# DUPIXENT

## Products Affected

- Dupixent

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | <p>Atopic dermatitis (AD) (init): Diagnosis (dx) of mod to severe AD. One of the following: a) Involvement of at least 10% body surface area (BSA), or b) SCORing Atopic Dermatitis (SCORAD) index value of at least 25. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication (eg, safety concerns, not indicated for patient's age/weight), or intolerance to at least one of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, or d) Eucrisa (crisaborole) ointment. Eosinophilic Asthma (EA) (init): Dx of mod to severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells/microliter. One of the following: 1) Patient has had two or more asthma exacerbations requiring systemic corticosteroids (eg, prednisone) within the past 12 mo, 2) Prior asthma-related hospitalization within the past 12 mo. Corticosteroid Dependent Asthma (CDA) (init): Dx of mod to severe asthma. Patient is currently dependent on oral corticosteroids for the treatment of asthma. EA, CDA (init): Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist (eg, montelukast), long-acting beta-2 agonist (LABA) (eg, salmeterol), tiotropium], OR b) One max-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Breo Ellipta (fluticasone/vilanterol)].</p> |
| Age Restrictions             | Asthma (initial): Patient is 6 years of age or older. AD (initial): Patient is 6 months or age or older. CRSwNP, PN: no age restriction. EoE (initial): Patient is at least 12 years of age.   |

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|                                |   |
|--------------------------------|---|
| <b>Prescriber Restrictions</b> | AD, Prurigo Nodularis (PN) (Initial): Prescribed by or in consultation with one of the following: dermatologist, allergist/immunologist. Asthma (initial, reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. CRSwNP (initial, reauth): Prescribed by or in consultation with an otolaryngologist, allergist/immunologist, or pulmonologist. EoE (initial): Prescribed by or in consultation with a gastroenterologist or allergist/immunologist. |
| <b>Coverage Duration</b>       | Plan year   |

|                              |   |
|------------------------------|---|
| <p><b>Other Criteria</b></p> | <p>Chronic rhinosinusitis with nasal polyposis (CRSwNP) (initial): Diagnosis of CRSwNP. Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (eg, fluticasone, mometasone). Used in combination with another agent for CRSwNP. Eosinophilic esophagitis (EoE) (initial): Dx of EoE. Patient has symptoms of esophageal dysfunction (eg, dysphagia, food impaction, gastroesophageal reflux disease [GERD]/heartburn symptoms, chest pain, abdominal pain). Patient has at least 15 intraepithelial eosinophils per high power field (HPF). Other causes of esophageal eosinophilia have been excluded. Patient weighs at least 40 kg. Trial and failure, contraindication, or intolerance to at least an 8-week trial of one of the following: proton pump inhibitors (eg, pantoprazole, omeprazole) or topical (esophageal) corticosteroids (eg, budesonide, fluticasone). PN (init): Diagnosis of PN. TF/C/I to one medium or higher potency topical corticosteroid. AD (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline. EA (reauth): Patient demonstrates positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications). CDA (reauth): Patient demonstrates a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in FEV1, reduction in oral corticosteroid dose). EA, CDA (reauth): Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications. CRSwNP (reauth): Patient demonstrates positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS, 0-8 scale], improvement in nasal congestion/obstruction score [NC, 0-3 scale]). Used in combination with another agent for CRSwNP. EoE (reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement of at least one of the following from baseline: symptoms (eg, dysphagia, food impaction, chest pain, heartburn), histologic measures (eg, esophageal intraepithelial eosinophil count), or endoscopic measures (eg, edema, furrows, exudates, rings, strictures). PN (reauth): Patient demonstrates positive clinical response to therapy.</p> |
|------------------------------|---|

# ENBREL

## Products Affected

- Enbrel
- Enbrel Mini
- Enbrel Sureclick

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month trial and failure, contraindication, or intolerance to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | RA (initial), PJIA (initial), AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a rheumatologist or dermatologist. Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist.  |

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|                          |  |
|--------------------------|--|
| <b>Coverage Duration</b> | Plan year  |
| <b>Other Criteria</b>    | <p>RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count.</p> |

# ENDARI

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## Products Affected

- Endari

| <b>PA Criteria</b>                  | <b>Criteria Details</b>                        |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.                  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of Sickle Cell Disease |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year                                      |
| <b>Other Criteria</b>               | N/A  |

# EPCLUSA

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## Products Affected

- Epclusa

- Sofosbuvir/velpatasvir

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Information required for review: genotype, prior treatments, cirrhosis status (including Child-Pugh class), desired treatment regimen, viral load, HIV status, liver transplant history. Requests will be reviewed against the most current edition of the American Association for the Study of Liver Diseases (AASLD) Infectious Diseases Society of America (IDSA) guidelines for Hepatitis C infection. Patients must be prescribed regimens recommended under these guidelines with the highest evidence rating in that category as of the date of the request. In cases where the request is for a lower evidence rated treatment, an explanation will be required as to why the higher rated regimen is not preferred. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 12 weeks  |
| <b>Other Criteria</b>               | N/A   |

# EPIDIOLEX

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## Products Affected

- Epidiolex

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex (TSC). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a neurologist.   |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# EPKINLY

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## Products Affected

- Epkinly

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma in adults. And patient has had 2 or more lines of systemic therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# EPOETIN

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## Products Affected

- Procrit
- Retacrit

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Determine if ESRD (B vs D) Patient has one of the following diagnosis: anemia associated with chronic renal failure, anemia associated with chemotherapy, Anemia secondary to zidovudine in HIV-infected patients, Reduction of allogeneic RBC transfusion in patients undergoing elective, non cardiac, non vascular surgery |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 6 months  |
| <b>Other Criteria</b>               | N/A   |

# ERIVEDGE

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## Products Affected

- Erivedge

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of metastatic basal cell carcinoma OR has a diagnosis of locally advanced basal cell carcinoma that has recurred following surgery or when the patient is not a candidate for surgery and radiation. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# ERLEADA

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## Products Affected

- Erleada

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has non-metastatic, castration-resistant prostate cancer or metastatic castration-sensitive prostate cancer. Patient will also be on concurrent gonadotropin-releasing hormone (GnRH) analog or had a bilateral orchiectomy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |



# ERLOTINIB

## Products Affected

- Erlotinib Hydrochloride TABS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For pancreatic cancer: Used first-line in locally advanced, unresectable, or metastatic cancer in combination with gemcitabine. For metastatic non-small cell lung cancer: not used in combination with platinum-based chemotherapy, tumors have EGFR exon 19 deletions or exon 21 substitution mutations. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# ESBRIET

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## Products Affected

- Esbriet

- Pirfenidone

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | The patient has a diagnosis of idiopathic pulmonary fibrosis. Liver function tests were performed prior to starting therapy.   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a pulmonologist  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | For renewal, the patient has not experienced AST or ALT elevations greater than 5 times the upper limit of normal or greater than 3 times the upper limit of normal with signs or symptoms of severe liver damage. |

# EVEROLIMUS

## Products Affected

- Everolimus TABS 10MG, 2.5MG, 5MG, 7.5MG

- Everolimus TBSO

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | Diagnosis of advanced metastatic renal cell carcinoma and patient has failed therapy (disease progressed) with Sutent or Nexavar OR Diagnosis of progressive pancreatic neuroendocrine tumors (pNET) that are unresectable OR progressive, well-differentiated, nonfunctional GI or lung endocrine tumors in patients with unresectable, locally advanced or metastatic disease OR Diagnosis of renal angiomyolipoma with tuberous sclerosis complex (TSC) and patient does not require immediate surgery OR Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer and patient is a postmenopausal woman and patient has failed treatment with Femara or Arimidex and the medication will be used in combination with Aromasin OR Diagnosis of subependymal giant cell astrocytoma (SEGA) associated with TSC that requires therapeutic intervention but is not a candidate for curative surgical resection OR diagnosis of tuberous sclerosis complex (TSC)-associated partial-onset seizures. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan year  |
| Other Criteria               | N/A  |

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# EXKIVITY

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## Products Affected

- Exkivity

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# FASENRA

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## Products Affected

- Fasenra
- Fasenra Pen

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has severe asthma with an eosinophilic phenotype. Patient is maintained with high dose inhaled corticosteroid or with medium to high dosed inhaled corticosteroid with a long-acting beta agonist (LABA). Patient has had at least two exacerbations in the past year or at least one exacerbation in the prior year while on daily oral corticosteroid treatment. |
| <b>Age Restrictions</b>             | 12 years of age or older   |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# FINTEPLA

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## Products Affected

- Fintepla

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a neurologist                                |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# FOTIVDA

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## Products Affected

- Fotivda

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of relapsed or refractory advanced renal cell carcinoma (RCC). Patient has tried at least 2 prior systemic therapies. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# FRUZAQLA

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## Products Affected

- Fruzaqla

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | Some FDA-approved Indications Only.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | Severe hepatic impairment (total bilirubin greater than 3 times ULN and any AST)  |
| <b>Required Medical Information</b> | Treatment of metastatic colorectal cancer in adults who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and an anti-EGFR therapy (if RAS wild type and medically appropriate) |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |



# GATTEX

## Products Affected

- Gattex

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Short Bowel Syndrome (SBS) (Initial): Diagnosis of SBS. Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient is dependent on parenteral nutrition/intravenous (PN/IV) support for at least 12 months. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | SBS (Init, reauth): Prescribed by or in consultation with a gastroenterologist.  |
| <b>Coverage Duration</b>            | SBS (Init): 6 months. SBS (Reauth): 12 months.   |
| <b>Other Criteria</b>               | SBS (Reauth): Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has had a reduction in weekly parenteral nutrition/intravenous (PN/IV) support from baseline while on therapy.                     |

# GAVRETO

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## Products Affected

- Gavreto

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of metastatic RET fusion-positive non-small cell lung cancer (NSCLC). Patient has a diagnosis of advanced or metastatic RET-mutant medullary thyroid cancer. Patient has a diagnosis of advanced or metastatic RET fusion positive thyroid cancer and is radioactive iodine-refractory (if radioactive iodine is appropriate). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# GILENYA

## Products Affected

- Fingolimod Hydrochloride
- Gilenya CAPS 0.25MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Recent occurrence (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, class III or IV heart failure. History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker. Baseline QTc interval greater than or equal to 500ms. Treatment with Class Ia or Class III anti-arrhythmic drugs. |
| <b>Required Medical Information</b> | Patient has a diagnosis of a relapsing form of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# GILOTRIF

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## Products Affected

- Gilotrif

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of previously untreated metastatic non-small cell lung cancer (NSCLC) with tumors expressing non-resistant epidermal growth factor receptor mutations. OR Patient has a diagnosis of metastatic squamous NSCLC and has been previously treated with platinum-based chemotherapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

## GLP1 (PREFERRED)

### Products Affected

- Bydureon Bcise
- Mounjaro
- Ozempic
- Rybelsus
- Soliqua 100/33
- Trulicity
- Victoza

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Type 2 Diabetes (initial): One of the following: a) For patients requiring ongoing treatment for type 2 diabetes mellitus, submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus, b) submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by one of the following laboratory values: A1c greater than or equal to 6.5%, fasting plasma glucose (FPG) greater than or equal to 126 mg/dL, 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during OGTT (oral glucose tolerance test). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | Reauth: Patient demonstrates positive clinical response to therapy  |

# GROWTH HORMONE

## Products Affected

- Genotropin
- Genotropin Miniquick
- Nutropin Aq Nuspin 10
- Nutropin Aq Nuspin 20
- Nutropin Aq Nuspin 5
- Omnitrope
- Zomacton

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Closed epiphyses in pediatric patients. Acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure. Active malignancy. Active proliferative or severe non-proliferative diabetic retinopathy. For Prader-Willi Syndrome only: severe obesity, history of upper airway obstruction or sleep apnea, or severe respiratory impairment.  |
| <b>Required Medical Information</b> | For CRI: patient is not post-kidney transplant. For TS: diagnosis confirmed by karyotyping. For PWS: diagnosis confirmed by genetic testing. For pediatric GHD, CRI, SHOXD, and NS, patient must meet one of the following: 1) height more than 3 SDS below mean for age and gender 2) Height more than 2 SDS below mean with growth velocity more than 1 SDS below mean, or 3) Growth velocity over 1 year 2 SDS below mean. For adult GHD: must meet one of the following: 1) Failed 2 standard GH stimulation tests 2) Panhypopituitarism or 3 or more pituitary hormone deficiencies 3) Childhood-onset GHD with known mutations, embryopathic lesions, or irreversible structural lesions/damage 4) Low pre-treatment IGF-1 and failed 1 stimulation test prior to starting treatment |
| <b>Age Restrictions</b>             | For SGA: patient is more than 2 years old.   |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |

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|                       |   |
|-----------------------|---|
| <b>Other Criteria</b> | For renewal of pediatric indications: final adult height has not been reached. For renewal of adult indications, patient has experienced an improvement or normalization of IGF-1 levels (not applicable to patients with panhypopituitarism) |
|-----------------------|---|

# HARVONI

## Products Affected

- Harvoni

- Ledipasvir/sofosbuvir

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Information required for review: genotype, prior treatments, cirrhosis status, desired treatment regimen, viral load, HIV status, liver transplant history, renal impairment status. Requests will be reviewed against the most current edition of the American Association for the Study of Liver Diseases (AASLD) Infectious Diseases Society of America (IDSA) guidelines for Hepatitis C infection. Patients must be prescribed regimens recommended under these guidelines as of the date of the request. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 12 or 24 weeks. 8 weeks per prescriber discretion  |
| <b>Other Criteria</b>               | N/A  |



# HETLIOZ

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## Products Affected

- Tasimelteon

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of non-24-hour sleep-wake disorder and meets the following: patient is totally blind in both eyes and unable to perceive light, for renewals: patient must experience an increase in total nighttime sleep or decreased daytime nap duration. Patient has a diagnosis of Smith-Magenis Syndrome (SMS) and has nighttime sleep disturbance. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Initial: 3 months, Renewal: plan year  |
| <b>Other Criteria</b>               | N/A  |

## HRM - ANTIDIABETICS

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### Products Affected

- Glyburide TABS
- Glyburide Micronized
- Glyburide/metformin Hydrochloride

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | The patient tried and failed to at least one of the following: glipizide, glipizide/metformin, or has contraindications to all alternatives. |
| <b>Age Restrictions</b>             | Applies to patients 65 years of age or older.  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | Patient will be monitored for hypoglycemia. Conservative dosing will be used to minimize hypoglycemic events.                                |

# HRM - DIGOXIN

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## Products Affected

- Digitek TABS 0.25MG
- Digox TABS 250MCG
- Digoxin TABS 250MCG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | The patient has tried a lower dose (less than or equal to 0.125mg daily) or has contraindications to a lower dose. |
| <b>Age Restrictions</b>             | Applies to patients 65 years of age or older.  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | The patient has been counseled on and does not have signs and symptoms of toxicity.                                |

## HRM - MUSCLE RELAXANTS

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### Products Affected

- Chlorzoxazone TABS 500MG
- Cyclobenzaprine Hydrochloride TABS

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | The prescriber must attest that the medication benefits outweigh the potential risks. |
| Age Restrictions             | Applies to patients 65 years of age or older.   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan year   |
| Other Criteria               | N/A   |

# HUMIRA

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## Products Affected

- Humira INJ 10MG/0.1ML, 20MG/0.2ML, 40MG/0.4ML, 40MG/0.8ML
- Humira Pediatric Crohns Disease Starter Pack
- Humira Pen
- Humira Pen-cd/uc/hs Starter
- Humira Pen-pediatric Uc Starter Pack
- Humira Pen-ps/uv Starter

| <b>PA Criteria</b>        | <b>Criteria Details</b>             |
|---------------------------|-------------------------------------|
| <b>Indications</b>        | All Medically-accepted Indications. |
| <b>Off-Label Uses</b>     | N/A                                 |
| <b>Exclusion Criteria</b> | N/A                                 |

|                                     |  |
|-------------------------------------|--|
| <b>Required Medical Information</b> | <p>Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. PsO (Initial): Diagnosis of moderate to severe chronic PsO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week TF/C/I to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), methotrexate. Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis.</p> |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | <p>RA, AS, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS (initial): Prescribed by or in consultation with a dermatologist. CD, UC (initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist.</p>  |
| <b>Coverage Duration</b>            | Plan year  |

|                              |   |
|------------------------------|---|
| <p><b>Other Criteria</b></p> | <p>Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), aminosalicylate [eg, mesalamine, olsalazine, sulfasalazine]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Hidradenitis suppurativa (HS), Uveitis (Reauth): Patient demonstrates positive clinical response to therapy. Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. CD (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. UC (Reauth): For patients who initiated therapy within the past 12 weeks: Patient demonstrates clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on therapy for longer than 12 weeks: Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.</p> |
|------------------------------|---|

# IBRANCE

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## Products Affected

- Ibrance

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has hormone receptor (HR)-positive, HER2-negative advanced or metastatic breast cancer. Ibrance will be used with an aromatase inhibitor as initial endocrine based therapy OR will be used with fulvestrant in patients with disease progression following endocrine therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |



# ICATIBANT

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## Products Affected

- Icatibant Acetate
- Sajazir

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of hereditary angioedema. Icatibant will be used for acute attacks of angioedema. Patient has been advised to seek immediate medical attention in addition to treatment with icatibant. Patient has been counseled to use no more than 3 doses in a 24 hour period. |
| <b>Age Restrictions</b>             | 18 years of age or older  |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# ICLUSIG

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## Products Affected

- Iclusig

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Patient must not have newly diagnosed chronic phase CML.   |
| <b>Required Medical Information</b> | Patient has a diagnosis of one of the following: accelerated phase or blast phase chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) for whom no other kinase inhibitors are indicated, T315I-positive CML (chronic, accelerated, or blast phase) or T315I-positive Ph+ ALL chronic phase, or CML with resistance or intolerance to at least 2 prior kinase inhibitors. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# IDHIFA

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## Products Affected

- Idhifa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of relapsed or refractory acute myeloid leukemia (AML). Patient has an isocitrate dehydrogenase-2 (IDH2) mutation. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# IMATINIB

## Products Affected

- Imatinib Mesylate

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis of one of the following in an adult: A) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML), B) Ph+ acute lymphoblastic leukemia (ALL), C) Myelodysplastic syndrome or myeloproliferative disease associated with platelet-derived growth factor receptor gene re-arrangements, D) Aggressive systemic mastocytosis without the D816V c-KIT mutation or with c-KIT mutational status unknown, E) Hypereosinophilic syndrome or chronic eosinophilic leukemia, F) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic, G) Gastrointestinal tumor (GIST) where patient has documented c-KIT (CD117) positive unresectable or metastatic malignant GIST or patient had resection of c-KIT positive GIST and imatinib will be used as an adjuvant therapy. Diagnosis of one of the following in a pediatric patient: A) Ph+ CML that is newly diagnosed in the chronic phase B) newly diagnosed Ph+ ALL. |
| <b>Age Restrictions</b>             | 18 years of age or younger - newly diagnosed CML in the chronic phase or newly diagnosed Ph+ ALL. 18 years of age or older for other indications.   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# IMBRUVICA

## Products Affected

- Imbruvica

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of mantle cell lymphoma (MCL) and patient has received at least one prior therapy. Diagnosis of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL). Diagnosis of CLL/SLL with 17p deletion. Diagnosis of Waldenstrom's macroglobulinemia (WM).<br>Diagnosis of marginal zone lymphoma in patients that have received at least one prior anti-CD20-based therapy such as rituximab. Diagnosis of chronic graft-versus-host disease after failure of one or more lines of systemic therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# INGREZZA

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## Products Affected

- Ingrezza

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Concomitant monoamine oxidase inhibitor (MAOI) or tetrabenazine.   |
| <b>Required Medical Information</b> | Patient has been clinically diagnosed with moderate to severe tardive dyskinesia including involuntary athetoid or choreiform movements. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Ingrezza is prescribed by or in consultation with a neurologist or psychiatrist.   |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | For renewal, patient must have improvement in symptoms.  |

# INLYTA

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## Products Affected

- Inlyta

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of advanced renal cell carcinoma (RCC). Patient has failed one prior systemic therapy, OR patient will use in combination with avelumab or pembrolizumab for first line treatment. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# INQOVI

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## Products Affected

- Inqovi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of Myelodysplastic syndrome (MDS). Patient has one of the following French- American-British subtypes: refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, or chronic myelomonocytic leukemia (CMML). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |



# INREBIC

## Products Affected

- Inrebic

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of intermediate-2 or high risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF). Thiamine level was assessed prior to starting treatment. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# INVEGA HAFYERA

## Products Affected

- Invega Hafyera

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient must have a diagnosis of schizophrenia. Patient must have been adequately treated with either once-a-month paliperidone palmitate extended-release injectable suspension (Invega Sustenna) for at least 4 months or an every-three-month paliperidone palmitate extended-release injectable suspension (Invega Trinza) for at least one 3 month cycle. Invega Hafyera will only be given once every 6 months. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# INVEGA TRINZA

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## Products Affected

- Invega Trinza

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient must have a diagnosis of schizophrenia. Patient must have been adequately treated with Invega Sustenna for at least 4 months. Invega Trinza will only be given once every 3 months. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# IRESSA

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## Products Affected

- Gefitinib

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has metastatic non-small cell lung cancer. The tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations. Patient is using gefitinib first line. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# IVERMECTIN

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## Products Affected

- Ivermectin TABS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>                    |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.        |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Using for treatment of COVID-19 infection. |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year                                  |
| <b>Other Criteria</b>               | N/A  |

# IVIG

## Products Affected

- Bivigam INJ 10%, 5GM/50ML
- Flebogamma Dif
- Gammagard Liquid
- Gammaked INJ 10GM/100ML, 1GM/10ML, 20GM/200ML, 5GM/50ML
- Gammaplex INJ 10GM/100ML, 10GM/200ML, 20GM/200ML, 20GM/400ML, 5GM/100ML, 5GM/50ML
- Gamunex-c
- Privigen

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | History of hypersensitivity to immune globulin or any component of the preparation.  |
| <b>Required Medical Information</b> | For a diagnosis of ITP: patient must have a trial of corticosteroids unless platelet count is less than 20,000 cells/mm <sup>3</sup> and bleeding has occurred.<br>For a diagnosis of hypogammaglobulinemia associated with B-cell chronic lymphocytic leukemia: IgG level is less than 500 mg/dL or patient has a history of infection. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.   |

# IWILFIN

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## Products Affected

- Iwilfin

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient is at risk of relapse of high-risk neuroblastoma in adult and pediatric patients AND have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# JAKAFI

## Products Affected

- Jakafi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of intermediate or high-risk myelofibrosis (including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis). OR Patient has a diagnosis of polycythemia vera and has had an inadequate response to or was intolerant of hydroxyurea. OR Patient has a diagnosis of acute graft-versus-host disease (GVHD) and has failed steroids. OR Patient has a diagnosis of chronic graft-versus-host disease and failed one or more lines of systemic therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |



# JAYPIRCA

## Products Affected

- Jaypirca

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of relapsed or refractory mantle cell lymphoma (MCL). And patient has had at least two lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor, in adults. OR Diagnosis of chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) after at least 2 lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a BCL-2 inhibitor, in adults. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# JUXTAPID

## Products Affected

- Juxtapid CAPS 10MG, 20MG, 30MG, 5MG

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | For initiation of treatment, moderate or severe hepatic impairment (eg, Child-Pugh B or C). For renewal, ALT or AST equal to or greater than 5 times the upper limit normal (ULN), or equal to greater than 3x ULN with signs or symptoms of liver toxicity or injury, increases in bilirubin greater than 2x ULN or active liver disease.  |
| <b>Required Medical Information</b> | For initiation of therapy, 1. Patient has a diagnosis of homozygous familial hypercholesterolemia confirmed by one of the following: A. documented mutations in both alleles at LDL receptor, ApoB, PCSK9, or ARH adapter protein gene locus, B. documented skin fibroblast LDL receptor activity less than 20% of normal, OR C. the following criteria are met: a) untreated LDL-C greater than 500 mg/dL or unknown AND b) triglyceride level less than 350 mg/dL AND c) tendon or cutaneous xanthomas at age 10 or younger OR d) both parents with a history of LDL-C greater than 190 mg/dL, AND 2. Patient has tried and had an inadequate response or intolerance to the maximum tolerated dose of a high potency statin and a PCSK9 inhibitor unless contraindicated. For renewal of therapy, 1. Patient meets all initial criteria AND 2. Current LDL-C is improved from the levels immediately prior to initiation of treatment with Juxtapid. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

Formulary ID: 24440, Version: 13, Effective Date: 07/01/2024

Last Updated: June 2024

# KALYDECO

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## Products Affected

- Kalydeco

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Statement from physician or lab results showing patient has cystic fibrosis with a CFTR gene mutation responsive to ivacaftor potentiation based on clinical and/or in vitro assay data. Patient is not homozygous for the F508del mutation in the CFTR gene. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# KEVZARA

## Products Affected

- Kevzara

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | Rheumatoid Arthritis (RA) (initial): Diagnosis of moderately to severely active RA. One of the following: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Polymyalgia Rheumatica (PMR) (initial): Diagnosis of PMR. One of the following: a) Patient has had an inadequate response to corticosteroids (e.g., prednisone), OR b) Patient cannot tolerate tapering of corticosteroids (e.g., prednisone). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | RA, PMR (initial): Prescribed by or in consultation with a rheumatologist  |
| Coverage Duration            | Plan year  |
| Other Criteria               | RA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PMR (reauth): Patient demonstrates positive clinical response to therapy.  |

# KINERET

## Products Affected

- Kineret

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) (initial): Diagnosis of NOMID AND dx of NOMID has been confirmed by one of the following: 1) NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3) gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation OR 2) Both of the following: a) two of the following clinical symptoms: urticaria-like rash, cold/stress triggered episodes, sensorineural hearing loss, musculoskeletal symptoms (e.g., arthralgia, arthritis, myalgia), chronic aseptic meningitis, or skeletal abnormalities (e.g., epiphyseal overgrowth, frontal bossing) AND b) elevated acute phase reactants (eg, erythrocyte sedimentation rate [ESR], C-reactive protein [CRP], serum amyloid A [SAA]). Deficiency of Interleukin-1 Receptor Antagonist (DIRA): Diagnosis of DIRA. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | RA (initial): Prescribed by or in consultation with a rheumatologist.<br>NOMID (initial): Prescribed by or in consultation with allergist/immunologist or rheumatologist or pediatrician.  |
| <b>Coverage Duration</b>            | RA, NOMID (initial): 6 months, (reauth): Plan Year DIRA: Plan Year   |

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|                       |   |
|-----------------------|---|
| <b>Other Criteria</b> | RA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. NOMID (reauth): Patient demonstrates positive clinical response to therapy. |
|-----------------------|---|

# KISQALI

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## Products Affected

- Kisqali
- Kisqali Femara 200 Dose
- Kisqali Femara 400 Dose
- Kisqali Femara 600 Dose

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of hormone receptor positive, human epidermal growth factor receptor 2 negative advanced or metastatic breast cancer and will be used with either an aromatase inhibitor as initial endocrine-based therapy OR fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men. Concomitant use with fulvestrant does not apply to Kisqali Femara Co-Pack requests. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# KORLYM

## Products Affected

- Korlym

- Mifepristone TABS 300MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | Not covered if patient is pregnant. Maximum dose: 1200mg daily, not to exceed 20mg/kg/day. Patient requires concomitant treatment with long-term corticosteroids (e.g., immunosuppression for organ transplant). History of unexplained vaginal bleeding. Endometrial hyperplasia with atypia or endometrial carcinoma. Concomitantly taking simvastatin, lovastatin, or a CYP3A substrate with a narrow therapeutic range (e.g., cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, or tacrolimus) |
| <b>Required Medical Information</b> | Patient has a diagnosis of endogenous Cushing's syndrome and has type 2 diabetes mellitus or glucose intolerance. Patient has failed surgery or is not a candidate for surgery. Statement from physician verifying that non-hormonal contraception will be used during treatment and for one month after discontinuation of therapy unless the patient has had surgical sterilization.  |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribing physician must be an endocrinologist  |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |



# KOSELUGO

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## Products Affected

- Koselugo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of neurofibromatosis type 1 and has symptomatic, inoperable plexiform neurofibromas. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# KRAZATI

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## Products Affected

- Krazati

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off-Label Uses</b>               | N/A                           |
| <b>Exclusion Criteria</b>           | N/A                           |
| <b>Required Medical Information</b> | N/A                           |
| <b>Age Restrictions</b>             | N/A                           |
| <b>Prescriber Restrictions</b>      | N/A                           |
| <b>Coverage Duration</b>            | Plan year                     |
| <b>Other Criteria</b>               | N/A                           |

# KUVAN

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## Products Affected

- Sapropterin Dihydrochloride

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.                                   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has hyperphenylalaninemia due to Phenylketonuria (PKU). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# LENVIMA

## Products Affected

- Lenvima 10 Mg Daily Dose
- Lenvima 12mg Daily Dose
- Lenvima 14 Mg Daily Dose
- Lenvima 18 Mg Daily Dose
- Lenvima 20 Mg Daily Dose
- Lenvima 24 Mg Daily Dose
- Lenvima 4 Mg Daily Dose
- Lenvima 8 Mg Daily Dose

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | Patient has a diagnosis of locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer. OR Patient has a diagnosis of advanced renal cell carcinoma (RCC) and has failed one prior anti-angiogenic therapy and will be used with everolimus or will be used first-line in combination with pembrolizumab, OR patient has a diagnosis of unresectable hepatocellular carcinoma (HCC) OR patient has a diagnosis of advanced endometrial carcinoma and will be used with pembrolizumab and does not have microsatellite instability-high or mismatch repair deficient and has had disease progression following prior systemic therapy. Lenvima will be used in combination with everolimus when used for RCC. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan year  |
| Other Criteria               | N/A  |

# LIDODERM

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## Products Affected

- Lidocaine PTCH 5%

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Diabetic neuropathy, cancer-related neuropathic pain.  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | The patient has a diagnosis of post-herpetic neuralgia, diabetic neuropathy, or cancer-related neuropathic pain. The patch will only be applied to intact skin |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# LONSURF

## Products Affected

- Lonsurf

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For a diagnosis of metastatic colorectal cancer: patient has been previously treated with a fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (such as FOLFOX, FOLFIRI, FOLFOXIRI) AND an anti-VEGF biological therapy (such as Avastin), if patient is RAS wild-type, patient has been previously treated with an anti-EGFR therapy. For a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma: patient has been treated with at least two prior lines of chemotherapy which included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# LOQTORZI

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## Products Affected

- Loqtorzi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | Some FDA-approved Indications Only.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Dx of metastatic or with recurrent, locally advanced nasopharyngeal carcinoma (NPC) in adults AND used as first-line treatment AND in combination with cisplatin and gemcitabine. Treatment (as a single agent) of recurrent unresectable or metastatic NPC in adults with disease progression on or after a platinum-containing chemotherapy |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# LORBRENA

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## Products Affected

- Lorbrena

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of anaplastic lymphoma kinase (ALK) positive metastatic non-small cell lung cancer (NSCLC). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |



# LUMAKRAS

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## Products Affected

- Lumakras

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) with a KRAS G12C mutation and has received at least one prior systemic therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# LYNPARZA

## Products Affected

- Lynparza TABS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | <p>Dx of one of the following: recurrent ovarian cancer (epithelial, fallopian tube, or primary peritoneal) after platinum-based chemotherapy OR Patient has a diagnosis of deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum based chemotherapy. OR Patient has a diagnosis of metastatic HER-2 negative breast cancer with deleterious or suspected deleterious germline BRCA-mutations and has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. OR Patient has a diagnosis of HER2-negative high risk early breast cancer with deleterious or suspected deleterious germline BRCA-mutations and has been treated with neoadjuvant or adjuvant chemotherapy. OR Patient has a diagnosis of patient has metastatic pancreatic adenocarcinoma with deleterious or suspected deleterious germline BRCA mutation who had at least 16 weeks of a first-line platinum-based chemotherapy regimen without disease progression. OR Patient has a diagnosis of advanced epithelial ovarian, fallopian tube or primary peritoneal cancer after a complete or partial response to first-line platinum-based chemotherapy, olaparib will be used in combination with bevacizumab, cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either a deleterious or suspected deleterious BRCA mutation, genomic instability. OR Patient has a diagnosis of deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer and disease has progressed following prior treatment with enzalutamide or abiraterone. OR Patient has a diagnosis of deleterious or suspected deleterious BRCA-mutated metastatic castration-resistant prostate cancer (mCRPC) AND will be used in combination with abiraterone and prednisone or prednisolone.</p> |
| <b>Age Restrictions</b>             | N/A   |

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Last Updated: June 2024

|                                |           |
|--------------------------------|-----------|
| <b>Prescriber Restrictions</b> | N/A       |
| <b>Coverage Duration</b>       | Plan year |
| <b>Other Criteria</b>          | N/A       |

# LYTGOBI

## Products Affected

- Lytgobi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis of unresctable, locally advacned, or metastatic intrahepatic cholangiocarcinoma. And disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangements. And patient has been previously treated. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# MAVYRET

## Products Affected

- Mavyret

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | Patient does not have moderate to severe hepatic impairment (Child-Pugh B or C).  |
| <b>Required Medical Information</b> | Information required for review: genotype, prior HCV treatments, cirrhosis status (including Child-Pugh class), desired treatment regimen, viral load, HIV status, liver transplant history. Requests will be reviewed against the most current edition of the American Association for the Study of Liver Diseases (AASLD) Infectious Diseases Society of America (IDSA) guidelines for Hepatitis C infection. Patients must be prescribed regimens recommended under these guidelines with the highest evidence rating in that category as of the date of the request. In cases where the request is for a lower evidence rated treatment, an explanation will be required as to why the higher rated regimen is not preferred. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 8, 12, or 16 weeks  |
| <b>Other Criteria</b>               | N/A   |

# MAYZENT

## Products Affected

- Mayzent

- Mayzent Starter Pack

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | Patients with CYP2C9 3/3, one of the following within the last 6 months: MI, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, Class III or IV HF, Mobitz Type II second degree, third degree AV block, or sick sinus syndrome unless pt has a functioning pacemaker |
| <b>Required Medical Information</b> | Patient has been tested for CYP2C9 variants. If the patients has CYP2C9 1/3 or 2/3 the patient will be maintained on 1mg daily.   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# MEKINIST

## Products Affected

- Mekinist

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has unresectable or metastatic melanoma with BRAF V600E or V600K mutations and Mekinist will be used as a single agent or with dabrafenib (Tafinlar) and patient has not received prior BRAF-inhibitor therapy (Zelboraf, Tafinlar), OR patient has melanoma with BRAF V600E or V600K mutations and involvement of lymph nodes and Mekinist will be used as adjuvant treatment with dabrafenib after complete resection and has not received prior BRAF-inhibitor therapy, OR patient has a diagnosis of BRAF V600E mutation positive metastatic non-small cell lung cancer and will use in combination with dabrafenib, OR patient has a diagnosis of BRAF V600E mutation-positive locally advanced or metastatic anaplastic thyroid cancer and will be used in combination with dabrafenib. OR patient has a diagnosis of unresectable or metastatic solid tumors with BRAF V600E mutation and patient has progressed following prior treatment and has no satisfactory alternative treatment options and will be used in combination with dabrafenib. OR patient has a diagnosis of low grade glioma with a BRAF V600E mutation AND will be used in combination with dabrafenib. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# MEKTOVI

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## Products Affected

- Mektovi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of unresectable or metastatic melanoma. Patient has a BRAF V600E or V600K mutation. Binimetinib (Mektovi) will be used in combination with encorafenib (Braftovi). Patient was not previously treated with a BRAF inhibitor or MEK inhibitor. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |



# MIGLUSTAT

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## Products Affected

- Miglustat

- Yargesa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of mild to moderate type 1 Gaucher disease. Enzyme replacement therapy is not a therapeutic option due to allergy, hypersensitivity, or poor venous access. Miglustat will be used as monotherapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# NERLYNX

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## Products Affected

- Nerlynx

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of early stage HER2-overexpressed breast cancer and has been on trastuzumab based therapy OR patient has a diagnosis of advanced or metastatic HER2-positive breast cancer and has received 2 or more prior anti-HER2 based regimens and will be used in combination with capecitabine. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# NEXAVAR

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## Products Affected

- Sorafenib

- Sorafenib Tosylate TABS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of one of the following: unresectable hepatocellular carcinoma, advanced renal cell carcinoma, or locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# NINLARO

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## Products Affected

- Ninlaro

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of multiple myeloma. Ixazomib will be used in combination with lenalidomide and dexamethasone. Patient has received at least one prior therapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# NORTHERA

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## Products Affected

- Droxidopa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient must have a diagnosis of neurogenic orthostatic hypotension caused by primary autonomic failure (due to Parkinson disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and nondiabetic autonomic neuropathy. Patient must also have tried midodrine. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a cardiologist or a neurologist.   |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# NUBEQA

## Products Affected

- Nubeqa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has non-metastatic, castration-resistant prostate cancer and patient will also be on concurrent gonadotropin-releasing hormone (GnRH) analog or had a bilateral orchiectomy. Patient has a diagnosis of metastatic hormone-sensitive prostate cancer (mHSPC) and will be using with docetaxel. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# NUCALA

## Products Affected

- Nucala

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of severe asthma with an eosinophilic phenotype and mepolizumab (Nucala) will be used as add-on treatment. For asthma: patient is maintained with high dose inhaled corticosteroid or with medium to high dosed inhaled corticosteroid with a long-acting beta agonist (LABA), and patient has had at least two exacerbations in the past year or at least one exacerbation in the prior year while on daily oral corticosteroid treatment. Patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA). Patient has a diagnosis of hypereosinophilic syndrome and has been diagnosed at least 6 months prior and does not have an identifiable nonhematologic secondary cause. Patient has a diagnosis of chronic rhinosinusitis with nasal polyps and this will be used as add-on maintenance treatment and patient had an inadequate response to nasal corticosteroids. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# NUEDEXTA

## Products Affected

- Nuedexta

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | Patient is currently using quinidine, quinine, mefloquine, monoamine oxidase inhibitors (MAOIs), or drugs that both prolong the QT interval and are metabolized by CYP2D6 (examples: thioridazine and pimozide). Patient has a prolonged QT interval or congenital long QT syndrome (LQTS), or heart failure or a history suggestive of torsades de pointes (TdP). Patient has complete atrioventricular (AV) block without an implanted pacemaker or is at high risk of complete AV block. |
| <b>Required Medical Information</b> | Diagnosis of pseudobulbar affect (PBA).   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |



# NUPLAZID

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## Products Affected

- Nuplazid CAPS
- Nuplazid TABS 10MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of Parkinson's disease and is experiencing at least one of the following: hallucinations, delusions. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# ODOMZO

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## Products Affected

- Odomzo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of locally advanced basal cell carcinoma (BCC). BCC has either recurred following surgery or radiation therapy or patient was not a candidate for surgery or radiation. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# OFEV

## Products Affected

- Ofev

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | The patient has a diagnosis of idiopathic pulmonary fibrosis, chronic fibrosing interstitial lung diseases with a progressive phenotype, or a diagnosis of systemic sclerosis-associated interstitial lung disease. Liver function tests were performed prior to starting therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a pulmonologist  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | For renewal, the patient has not experienced AST or ALT elevations greater than 5 times the upper limit of normal or greater than 3 times the upper limit of normal with signs or symptoms of severe liver damage.   |

# OGSIVEO

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## Products Affected

- Ogsiveo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | Some FDA-approved Indications Only.                                       |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Dx of progressing desmoid tumors in adults who require systemic treatment |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# OJEMDA

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## Products Affected

- Ojemda

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off-Label Uses</b>               | N/A                           |
| <b>Exclusion Criteria</b>           | N/A                           |
| <b>Required Medical Information</b> | N/A                           |
| <b>Age Restrictions</b>             | N/A                           |
| <b>Prescriber Restrictions</b>      | N/A                           |
| <b>Coverage Duration</b>            | Plan Year                     |
| <b>Other Criteria</b>               | N/A                           |

# OJJAARA

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## Products Affected

- Ojjaara

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | Some FDA-approved Indications Only.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF (post-polycythemia vera [PV] and post-essential thrombocythemia [ET]), in adults with anemia. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# ONUREG

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## Products Affected

- Onureg

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of acute myeloid leukemia and achieved first complete remission or complete remission with incomplete blood count recovery following intensive induction chemotherapy and patient is not able to complete intensive curative therapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# OPSUMIT

## Products Affected

- Opsumit

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has pulmonary arterial hypertension (PAH), World Health Organization Group I disease. PAH was confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.). Liver function tests were performed prior to starting therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |



# ORENCIA IV

## Products Affected

- Orencia INJ 250MG

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Acute graft versus host disease (aGVHD): Used for prophylaxis of aGVHD. Patient will receive hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor. Recommended antiviral prophylactic treatment for Epstein-Barr Virus (EBV) reactivation (e.g., acyclovir) will be administered prior to Orencia and continued for six months after HSCT. Used in combination with both of the following: calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate. |
| <b>Age Restrictions</b>             | aGVHD: Patient is 2 years of age or older   |
| <b>Prescriber Restrictions</b>      | RA, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist.  |
| <b>Coverage Duration</b>            | Plan year   |

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|                       |   |
|-----------------------|---|
| <b>Other Criteria</b> | RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. |
|-----------------------|---|

# ORENCIA SC

## Products Affected

- Orenzia INJ 125MG/ML, 50MG/0.4ML, 87.5MG/0.7ML

- Orenzia Clickject

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | RA, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist.  |
| <b>Coverage Duration</b>            | Plan year   |

|                       |   |
|-----------------------|---|
| <b>Other Criteria</b> | RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. |
|-----------------------|---|

# ORENITRAM

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## Products Affected

- Orenitram
- Orenitram Titration Kit Month 1
- Orenitram Titration Kit Month 2
- Orenitram Titration Kit Month 3

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | Patient has a diagnosis of severe hepatic impairment (Child Pugh Class C).  |
| <b>Required Medical Information</b> | Diagnosis of pulmonary arterial hypertension that was confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# ORGOVYX

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## Products Affected

- Orgovyx

| <b>PA Criteria</b>                  | <b>Criteria Details</b>                              |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.                        |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of advanced prostate cancer. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# ORKAMBI

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## Products Affected

- Orkambi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has cystic fibrosis and is homozygous for the F508del mutation in the CFTR gene. Patient had baseline ALT, AST, and bilirubin assessed. |
| <b>Age Restrictions</b>             | 1 year of age or older  |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# ORSERDU

## Products Affected

- Orserdu

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of advanced or metastatic breast cancer in postmenopausal women or adult men. And disease is ER-positive and HER-2 negative. Patient has the presence of ESR1 mutation as detected by an approved test. And disease has progressed following at least one line of endocrine therapy [e.g., Faslodex (fulvestrant), Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)]. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |



# OSPHERA

## Products Affected

- Ospheana

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Dyspareunia (initial): Diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause. Vaginal dryness (initial): Diagnosis of moderate to severe vaginal dryness due to vulvar and vaginal atrophy associated with menopause. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | All uses (Initial, reauth): 12 months   |
| <b>Other Criteria</b>               | Dyspareunia, Vaginal dryness (reauth): Documentation of positive clinical response to therapy.  |

# OTEZLA

## Products Affected

- Otezla

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Psoriatic arthritis (PsA) (initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (initial): Diagnosis of plaque psoriasis AND Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. Oral ulcers associated with Behcet's Disease (Initial): Diagnosis of Behcet's Disease. Patient has active oral ulcers.   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque psoriasis (init): Prescribed by or in consultation with a dermatologist.   |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | PsA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. Oral ulcers associated with Behcet's Disease (reauth): Patient demonstrates positive clinical response to therapy (eg, reduction in pain from oral ulcers or reduction in number of oral ulcers). |

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# OXANDROLONE

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## Products Affected

- Oxandrolone TABS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications. |
| <b>Off-Label Uses</b>               | Adjunctive therapy for severe burns, AIDS related cachexia.        |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# PEMAZYRE

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## Products Affected

- Pemazyre

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement and patient has been previously treated. Patient has a diagnosis of relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with fibroblast growth factor receptor 1 (FGFR1) rearrangement. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# PIQRAY

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## Products Affected

- Piqray 200mg Daily Dose
- Piqray 250mg Daily Dose
- Piqray 300mg Daily Dose

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of metastatic breast cancer. Patient has HR positive and HER2 negative markers. Patient has PIK3CA mutated disease. Progressed on or after endocrine based regimen. Piqray will be used with fulvestrant. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# POMALYST

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## Products Affected

- Pomalyst

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For multiple myeloma: 1) Patient received prior therapy with Velcade (bortezomib) AND Revlimid (lenalidomide), 2) disease has progressed during or within 60 days of completion of last therapy 3) Will be used in combination with dexamethasone. For Kaposi sarcoma (KS): patient has AIDS-related KS after failure of highly active antiretroviral therapy or patient is HIV-negative. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# PRALUENT

## Products Affected

- Praluent

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of primary hyperlipidemia, homozygous familial hypercholesterolemia, or alirocumab will be used to reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in patients with established cardiovascular disease. Patient is on maximally tolerated statin therapy or has zero tolerance to statin therapy. Patient will be started on the 75mg dose. For a diagnosis of clinical atherosclerotic cardiovascular disease or primary hyperlipidemia: patient has tried at least two statins (rosuvastatin, atorvastatin, simvastatin, pravastatin, lovastatin, or fluvastatin) |
| <b>Age Restrictions</b>             | 18 years of age or older  |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |



# PROMACTA

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## Products Affected

- Promacta

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | Use in the management of thrombocytopenia in myelodysplastic syndrome (MDS).  |
| <b>Required Medical Information</b> | Patient has a diagnosis of chronic immune thrombocytopenic purpura (ITP) and meets both of the following: baseline platelet count less than 50,000/mcL, had an insufficient response to either corticosteroids, immunoglobulins, or splenectomy. Patient has a diagnosis of severe aplastic anemia with a platelet count less than 30,000/mcL. Patient has a diagnosis of thrombocytopenia in a patient with chronic hepatitis C. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# PROVIGIL

## Products Affected

- Modafinil TABS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis of excessive sleepiness associated with obstructive sleep apnea (OSA)/hypopnea syndrome and documentation of residual excessive sleepiness OR Diagnosis of excessive sleepiness associated with narcolepsy and patient has tried and failed, is unable to tolerate, or has contraindication(s) to at least one other central nervous system stimulant (e.g., methylphenidate, mixed amphetamine salts, dextroamphetamine) OR Diagnosis of excessive sleepiness associated with shift work disorder. |
| <b>Age Restrictions</b>             | 17 years of age or older.   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# QINLOCK

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## Products Affected

- Qinlock

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of advanced gastrointestinal stromal tumor (GIST). Patient has received 3 or more prior kinase inhibitors, including imatinib. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# QUININE

## Products Affected

- Quinine Sulfate CAPS 324MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Babesiosis, uncomplicated Plasmodium vivax malaria.   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of uncomplicated Plasmodium falciparum malaria, uncomplicated Plasmodium vivax malaria, or babesiosis. Patient is not prescribed quinine for the treatment or prevention of leg cramps. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# RECORLEV

## Products Affected

- Recorlev

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Initial: Diagnosis of Cushing's syndrome. Patient is being treated for endogenous hypercortisolemia (e.g., pituitary adenoma, ectopic tumor, adrenal adenoma). One of the following: 1) Patient is not a candidate for surgery, OR 2) Surgery has not been curative. Trial and failure of at least 30 days, or intolerance to oral ketoconazole. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an endocrinologist   |
| <b>Coverage Duration</b>            | Initial 6 months, Reauth:Plan Year   |
| <b>Other Criteria</b>               | Reauth: Patient demonstrates positive clinical response to therapy   |

# REGRANEX

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## Products Affected

- Regranex

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has diabetes. Patient has neuropathic ulcers on the lower extremity that extend into the subcutaneous tissue or beyond and have an adequate blood supply (i.e. is not an ischemic ulcer). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 20 weeks  |
| <b>Other Criteria</b>               | N/A   |

# RELISTOR

## Products Affected

- Relistor

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | Patient with known or suspected mechanical GI obstruction and at increased risk of recurrent obstruction.   |
| <b>Required Medical Information</b> | Patient has a diagnosis of opioid induced constipation with either chronic non cancer pain or advanced illness or pain caused by cancer who are receiving palliative care, when response to laxative therapy has not been sufficient. Patient has had an inadequate response to lubiprostone or Movantik. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# REPATHA

## Products Affected

- Repatha
- Repatha Pushtronex System
- Repatha Sureclick

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | Patient has a diagnosis of heterozygous or homozygous familial hypercholesterolemia (HeFH or HoFH), primary hyperlipidemia, or clinical atherosclerotic cardiovascular disease (ASCVD, defined as having at least one of the following: ACS, history of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, or peripheral arterial disease presumed to be of atherosclerotic origin) and requires additional lowering of LDL cholesterol. Patient is on maximally tolerated statin therapy or has zero tolerance to statin therapy. For a diagnosis of clinical atherosclerotic cardiovascular disease or primary hyperlipidemia: patient has tried at least two statins (rosuvastatin, atorvastatin, simvastatin, pravastatin, lovastatin, or fluvastatin). |
| Age Restrictions             | Patient is 10 years of age or older  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan year  |
| Other Criteria               | N/A  |



# RESPIRATORY PDE-5 INHIBITOR

## Products Affected

- Alyq
- Sildenafil Citrate SUSR
- Sildenafil Citrate TABS 20MG
- Tadalafil TABS 20MG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | Receiving nitrate therapy (includes intermittent use)   |
| Required Medical Information | Diagnosis of pulmonary arterial hypertension that was confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.) AND Patient has (WHO Group I) PAH. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan year   |
| Other Criteria               | N/A   |

# RETEVMO

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## Products Affected

- Retevmo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of metastatic non-small cell lung cancer with RET fusion-positive disease. OR patient has a diagnosis of advanced or metastatic RET-mutant medullary thyroid cancer. OR patient has a diagnosis of advanced or metastatic RET fusion-positive thyroid cancer and is refractory to radioactive iodine (if radioactive iodine is appropriate). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# REVLIMID

## Products Affected

- Lenalidomide

- Revlimid

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of multiple myeloma and medication will be used in combination with dexamethasone or as maintenance therapy after autologous hematopoietic stem cell transplant. OR Diagnosis of transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5 q cytogenetic abnormality with or without additional cytogenetic abnormalities. OR Diagnosis of mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib. AND Patient is not using the medication for the treatment of chronic lymphocytic leukemia. OR Patient has a diagnosis of follicular or marginal zone lymphoma that has been previously treated and will be used with a rituximab product. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# REZLIDHIA

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## Products Affected

- Rezlidhia

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off-Label Uses</b>               | N/A                           |
| <b>Exclusion Criteria</b>           | N/A                           |
| <b>Required Medical Information</b> | N/A                           |
| <b>Age Restrictions</b>             | N/A                           |
| <b>Prescriber Restrictions</b>      | N/A                           |
| <b>Coverage Duration</b>            | Plan Year                     |
| <b>Other Criteria</b>               | N/A                           |

# REZUROCK

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## Products Affected

- Rezurock

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of chronic graft-versus-host disease (chronic GVHD). Patient has had a failure of at least 2 prior lines of systemic therapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# RINVOQ

## Products Affected

- Rinvoq

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | Rheumatoid arthritis (RA) (init): Diagnosis (Dx) of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Psoriatic arthritis (PsA) (init): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Ankylosing spondylitis (AS) (init): Dx of active AS. Non-radiographic axial spondyloarthritis (NRAS, init): Dx of active NRAS. Patient has signs of inflammation. Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Cimzia). AS, NRAS (init): Minimum duration of a one-month TF/C/I to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. Atopic dermatitis (AD) (init): Dx of moderate to severe AD. One of the following: a) Involvement of at least 10% body surface area (BSA), or b) SCORing Atopic Dermatitis (SCORAD) index value of at least 25. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), C/I to at least one of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, or d) Eucrisa ointment. One of the following: 1) Trial and failure of a minimum 12-week supply of at least one systemic drug product for the treatment of AD (examples include, but are not limited to, Adbry, Dupixent, etc.), OR 2) Patient has a contraindication, intolerance, or treatment is inadvisable with both of the following FDA-approved AD therapies: Adbry and Dupixent. Not used in combination with other JAK inhibitors, biologic immunomodulators, or other immunosuppressants (eg, azathioprine, cyclosporine). |
| Age Restrictions             | AD (initial): Patient is 12 years of age or older  |

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|                                |  |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | RA, AS, NRAS (init): Prescribed by or in consultation with a rheumatologist. PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. AD (init): Prescribed by or in consultation with a dermatologist or allergist/immunologist. UC (init): Prescribed by or in consultation with a gastroenterologist. |
| <b>Coverage Duration</b>       | Plan year  |

|                              |   |
|------------------------------|---|
| <p><b>Other Criteria</b></p> | <p>RA, PsA, AS (init): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Enbrel, Humira). RA, PsA, AS, NRAS (init, reauth): Not used in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or potent immunosuppressants (eg, azathioprine, cyclosporine). Ulcerative colitis (UC) (init): Dx of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine), azathioprine, or corticosteroids (eg, prednisone). Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Humira). Not used in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine). RA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS, NRAS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. AD (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline. Not used in combination with other JAK inhibitors, biologic immunomodulators, or other immunosuppressants (eg, azathioprine, cyclosporine). UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. Not used in combination with other JAK inhibitors, biological therapies for UC, or potent immunosuppressants (eg, azathioprine, cyclosporine).</p> |
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# ROZLYTREK

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## Products Affected

- Rozlytrek

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of metastatic non-small cell lung cancer with ROS1-positive tumors. OR Patient has solid tumors that meet the following: have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, patient has either progressed following treatment or has no satisfactory alternative therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# RUBRACA

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## Products Affected

- Rubraca

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of metastatic castration resistant prostate cancer with a deleterious BRCA mutation and has been treated with androgen receptor directed therapy and taxane based chemotherapy. OR rucaparib will be used for the maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer after a complete or partial response to platinum-based chemotherapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# RYDAPT

## Products Affected

- Rydapt

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of new onset acute myeloid leukemia (AML) that is FLT3 mutation positive, aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, mast cell leukemia. For patients with AML, midostaurin will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy. Midostaurin will not be used as a single-agent induction for AML. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# SCSEMBLIX

## Products Affected

- Scemblix

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs) OR Ph+ CML in CP with the T315I mutation. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# SKYRIZI

## Products Affected

- Skyrizi INJ 150MG/ML, 180MG/1.2ML, 360MG/2.4ML, 75MG/0.83ML
- Skyrizi Pen

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active CD. Will be used as a maintenance dose following the intravenous induction doses. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. CD (Initial): Prescribed by or in consultation with a gastroenterologist.  |
| <b>Coverage Duration</b>            | Plan year   |

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|-----------------------|--|
| <b>Other Criteria</b> | Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. CD (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. |
|-----------------------|--|

# SODIUM OXYBATE

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## Products Affected

- Sodium Oxybate

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | Taking alcohol or sedative hypnotic agents while taking sodium oxybate.   |
| <b>Required Medical Information</b> | Patient has a diagnosis of narcolepsy with either cataplexy or excessive daytime sleepiness. For patients with a diagnosis of excessive daytime sleepiness, patient has had a previous trial with or a contraindication, intolerance, or allergy to modafinil, armodafinil, methylphenidate, dextroamphetamine, or mixed amphetamine salts. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# SOMATULINE

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## Products Affected

- Lanreotide Acetate
- Somatuline Depot

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of either Acromegaly or gastroenteropancreatic neuroendocrine tumors (GEP-NETs), or carcinoid syndrome. For acromegaly, patient has had an inadequate or partial response to surgery and/or radiotherapy or patient was not a candidate for surgery or radiotherapy. For GEP-NETs, tumors are unresectable, well- or moderately-differentiated, locally advanced or metastatic. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |



# SPRYCEL

## Products Affected

- Sprycel

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Gastrointestinal stromal tumor (GIST).  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Newly diagnosed adults with Philadelphia chromosome-positive chronic myelogenous leukemia (CML) in chronic phase. Adults with chronic, accelerated, or myeloid or lymphoid blast phase Philadelphia chromosome-positive CML with resistance or intolerance to prior therapy including imatinib. Adults with diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy. Pediatric patients with a diagnosis of Philadelphia chromosome-positive CML in chronic phase or newly diagnosed Philadelphia chromosome-positive ALL in combination with chemotherapy. For patients with GIST, patient must have progressed on imatinib or sunitinib. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# STELARA

## Products Affected

- Stelara INJ 45MG/0.5ML, 90MG/ML

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Plaque psoriasis (Initial - 45mg/0.5mL): Diagnosis of moderate to severe plaque psoriasis. Plaque psoriasis (Initial - 90mg/1mL): Diagnosis of moderate to severe plaque psoriasis. Patient's weight is greater than 100 kg (220 lbs). Plaque psoriasis (Initial): One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. Psoriatic arthritis (PsA) (Initial - 45mg/0.5mL): Diagnosis of active PsA. PsA (Initial - 90mg/1mL): Diagnosis of active PsA. Patient's weight is greater than 100 kg (220 lbs). Diagnosis of co-existent moderate to severe psoriasis. PsA (Initial): One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active Crohn's disease. Will be used as a maintenance dose following the intravenous induction dose. |
| <b>Age Restrictions</b>             | Plaque psoriasis, PsA: Patient is 6 years of age or older.  |
| <b>Prescriber Restrictions</b>      | Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. CD and UC (initial): Prescribed by or in consultation with a gastroenterologist.   |
| <b>Coverage Duration</b>            | Plan year   |

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|-----------------------|--|
| <b>Other Criteria</b> | Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Will be used as a maintenance dose following the intravenous induction dose. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD (Reauth), UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. |
|-----------------------|--|

# STELARA IV

## Products Affected

- Stelara INJ 130MG/26ML

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Crohn's Disease (CD): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CAI) greater than 220. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, azathioprine, methotrexate, corticosteroid (eg, prednisone). Ulcerative Colitis (UC): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), or an aminosalicylate [eg, mesalamine, olsalazine, sulfasalazine]. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a gastroenterologist.  |
| <b>Coverage Duration</b>            | One time   |
| <b>Other Criteria</b>               | Stelara is to be administered as an intravenous induction dose. Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's Disease/ulcerative colitis: 260 mg for patients weighing 55 kg or less, 390 mg for patients weighing more than 55 kg to 85 kg, or 520 mg for patients weighing more than 85 kg.  |

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# STIVARGA

## Products Affected

- Stivarga

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of: A) metastatic colorectal cancer AND patient has previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan -based therapy, an anti-vascular endothelial growth factor (VEGF) therapy, and, if KRAS wild type, an anti-epidermal growth factor receptor (EGFR) therapy or B) gastrointestinal stromal tumors that is locally advanced, unresectable or metastatic AND patient has tried and had an inadequate response, contraindication or intolerance to imatinib and sunitinib or C) hepatocellular carcinoma and has been previously treated with sorafenib. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# SUTENT

## Products Affected

- Sunitinib Malate

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis of advanced/metastatic renal cell carcinoma or as an adjuvant treatment after nephrectomy. Diagnosis of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib. Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in a patient with unresectable locally advanced or metastatic disease. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# SYMLIN

## Products Affected

- Symlinpen 120
- Symlinpen 60

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of type 1 or type 2 diabetes mellitus. Patient is currently receiving optimal mealtime insulin therapy. Patient has had an inadequate treatment response to insulin. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# TABRECTA

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## Products Affected

- Tabrecta

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of metastatic non-small cell lung cancer whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |



# TAFINLAR

## Products Affected

- Tafinlar

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation and will be used in combination with trametinib, OR a diagnosis of unresectable or metastatic melanoma AND will be used as monotherapy in patients with the BRAF V600E mutation OR dabrafenib will be used in combination with trametinib in patients with BRAF V600E or V600K mutations, OR patient has a diagnosis of melanoma with BRAF V600E or V600K mutations with lymph node involvement and will be used in combination with trametinib after complete resection, OR patient has a diagnosis of locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutations and will be used with trametinib. OR patient has a diagnosis of unresectable or metastatic solid tumors with BRAF V600E mutation and patient has progressed following prior treatment and has no satisfactory alternative treatment options and will be used in combination with trametinib. OR patient has a diagnosis of low grade glioma with a BRAF V600E mutation AND will be used in combination with trametinib. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# TAGRISSEO

## Products Affected

- Tagrisso

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of non-small cell lung cancer (NSCLC) and meets the following criteria: patient will use osimertinib as adjuvant therapy after tumor resection and tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, osimertinib will be used first-line in metastatic disease and tumors have EGFR exon 19 deletions or exon 21 L858R mutations, or osimertinib will be used in patients with EGFR T790M mutation-positive metastatic disease and patient has progressed on or after EFGR tyrosine kinase inhibitor therapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# TALZENNA

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## Products Affected

- Talzenna

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of locally advanced or metastatic breast cancer. Patient has deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated human epidermal growth factor receptor 2 (HER2) negative disease. OR Patient has a diagnosis of homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer AND will be used in combination with enzalutamide. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# TARGRETIN

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## Products Affected

- Bexarotene GEL

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For gel: patient has a diagnosis of stage 1A or 1B cutaneous T-cell lymphoma that is refractory or persistent after treatment with other therapies or has not tolerated other therapies. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# TASIGNA

## Products Affected

- Tasigna

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | Uncorrected hypokalemia or hypomagnesemia, long QT syndrome. Use of concomitant drugs known to prolong the QT interval or strong CYP3A4 inhibitors.   |
| <b>Required Medical Information</b> | Patient (age 1 or older) has a diagnosis of newly diagnosed Philadelphia chromosome positive CML in chronic phase OR adult patient with a diagnosis of chronic phase or accelerated phase Philadelphia chromosome positive CML in patients that are resistant or intolerant to imatinib OR pediatric patient with a diagnosis of chronic or accelerated phase Philadelphia chromosome positive CML in patients that are resistant or intolerant to prior tyrosine-kinase inhibitor therapy. |
| <b>Age Restrictions</b>             | Age 1 and older for pediatric indications   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# TAVALISSE

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## Products Affected

- Tavalisse

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of chronic immune thrombocytopenia (ITP).<br>Patient had an insufficient response to a previous treatment. |
| <b>Age Restrictions</b>             | 18 years of age or older   |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# TAZVERIK

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## Products Affected

- Tazverik

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of metastatic or locally advanced epithelioid sarcoma and is not eligible for complete resection. OR Patient has a diagnosis of relapsed or refractory follicular lymphoma with one of the following: tumors are positive for an EZH2 mutation and patient received at least 2 prior systemic therapies, or patient has no satisfactory alternative treatment options. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# TECFIDERA

## Products Affected

- Dimethyl Fumarate CPDR
- Dimethyl Fumarate Starterpack CDPK 0

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of a relapsing form of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. Patient must have a complete blood count within the past 6 months before initiation. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | To continue therapy, the patient must demonstrate stabilization or improvement while on dimethyl fumarate.  |



# TEPMETKO

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## Products Affected

- Tepmetko

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC) with mesenchymal-epithelial transition (MET) exon 14 skipping alterations. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# TETRABENAZINE

## Products Affected

- Tetrabenazine

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Tardive dyskinesia, Tourette's syndrome.   |
| <b>Exclusion Criteria</b>           | Actively suicidal or has untreated or inadequately treated depression. Impaired hepatic function. Concomitant monoamine oxidase inhibitor (MAOI) or use within 14 days of stopping MAOI. Concomitant reserpine or use within 20 days of stopping reserpine.  |
| <b>Required Medical Information</b> | Diagnosis of chorea associated with Huntington's disease. If treating for tardive dyskinesia, require failure of at least one previous therapy (e.g., amantadine, benzodiazepines, haloperidol, atypical antipsychotics, etc.) or Gilles de la Tourette's syndrome with failure or least one previous therapy (e.g., antipsychotic agents, clonidine). Patients who require doses greater than 50 mg/day will be genotyped for CYP2D6 to determine whether the patient is a poor, intermediate or extensive metabolizer. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | For renewal, patient must have a lack of disease progression or have improvement in symptoms.  |

# THALOMID

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## Products Affected

- Thalomid

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of: A) multiple myeloma that is newly diagnosed and is receiving concurrent dexamethasone B) acute treatment of cutaneous manifestations of moderate to severe erythema nodosum leprosum C) Maintenance therapy for prevention and suppression of the cutaneous manifestations of erythema nodosum leprosum recurrence. Thalidomide will not be used as monotherapy for erythema nodosum leprosum treatment if the member has moderate to severe neuritis |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# TIBSOVO

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## Products Affected

- Tibsovo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation.<br>OR Patient has a diagnosis of newly-diagnosed AML with a susceptible IDH1 mutation in a patient that is at least 75 years old or who has comorbidities that preclude the use of intensive induction chemotherapy.<br>OR Patient has a diagnosis of previously treated, locally advanced or metastatic cholangiocarcinoma with an IDH1 mutation. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# TRANSMUCOSAL FENTANYL PRODUCTS

## Products Affected

- Fentanyl Citrate Oral Transmucosal

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | Patient has active cancer and TIRF will be used for breakthrough cancer pain. Patient has tried and failed or has contraindications to at least 2 of the following short acting narcotics: oxycodone, morphine sulphate, hydromorphone. Long-Acting opioid is being prescribed The patient is opioid tolerant (Patients are considered opioid tolerant if they have been taking at least 60 mg of oral morphine per day, 25 mcg of transdermal fentanyl/hr, 30 mg of oral oxycodone daily, 8 mg of oral hydromorphone daily, 25 mg oral oxymorphone daily or an equianalgesic dose of another opioid for a week or longer.). |
| Age Restrictions             | 16 years of age or older   |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan year  |
| Other Criteria               | N/A  |

# TRIKAFTA

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## Products Affected

- Trikafta

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of cystic fibrosis and at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on in vitro data. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# TRUQAP

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## Products Affected

- Truqap

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | Some FDA-approved Indications Only.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Dx of locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer in adults with one or more PIK3CA/AKT1/PTEN-alteration (as detected by an approved test) AND following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy AND used in combination with fulvestrant |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# TUKYSA

## Products Affected

- Tukysa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | The patient has a diagnosis of advanced unresectable or metastatic breast cancer. Patient has HER2-positive disease and has received one or more prior anti-HER2-based regimen. Tukysa will be used in combination with trastuzumab and capecitabine. OR Patient has a diagnosis of RAS wild-type, HER2-positive unresectable or metastatic colorectal cancer AND will be used in combination with trastuzumab AND the disease has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |



# TURALIO

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## Products Affected

- Turalio

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of tenosynovial giant cell tumor (TGCT) and be symptomatic. Patients disease must be associated with severe morbidity or functional limitations and not be amenable to improvement with surgery. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# TYKERB

## Products Affected

- Lapatinib Ditosylate

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of advanced or metastatic breast cancer with overexpression of HER2 AND lapatinib will be used with capecitabine AND patient has received prior therapy with an anthracycline, a taxane, and trastuzumab. OR Patient is postmenopausal with a diagnosis of hormone receptor positive metastatic breast cancer with overexpression of HER2 AND lapatinib will be used with letrozole. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# UBRELVY

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## Products Affected

- Ubrelvy

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of migraine with or without aura. Will be used for the acute treatment of migraine. Will not be used for preventive treatment of migraine. Patient has fewer than 15 headache days per month. Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or a contraindication to all triptans. Medication will not be used in combination with another oral CGRP inhibitor. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist   |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# UPTRAVI

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## Products Affected

- Uptravi

- Uptravi Titration Pack

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis of pulmonary arterial hypertension (WHO Group I) that was confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# VANFLYTA

## Products Affected

- Vanflyta

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of acute myeloid leukemia (AML). And patient has a FMS-like tyrosine kinase 3 (FLT3) internal tandem duplication (ITD)-positive (as detected by an approved test). And will be used in combination with standard cytarabine and anthracycline (e.g., daunorubicin, idarubicin) induction and cytarabine consolidation. And will be used as maintenance monotherapy following consolidation chemotherapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# VENCLEXTA

## Products Affected

- Venclexta

- Venclexta Starting Pack

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | Must not be on a strong CYP3A inhibitor (such as ketoconazole, conivaptan, clarithromycin, indinavir, itraconazole, lopinavir, ritonavir, telaprevir, posaconazole, or voriconazole) at Venclexta initiation and during Venclexta ramp-up phase.  |
| <b>Required Medical Information</b> | Patient has a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). Patient has a diagnosis of newly-diagnosed acute myeloid leukemia (AML) in adults 75 or older or who have comorbidities that preclude the use of intensive induction chemotherapy AND Venclexta will be used in combination with azacitidine, or decitabine, or low-dose cytarabine. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# VERZENIO

## Products Affected

- Verzenio

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has advanced or metastatic hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative breast cancer AND patient will use in combination with an aromatase inhibitor as initial treatment in adults OR will be used in combination with fulvestrant in patients that had disease progression following endocrine therapy OR patient has metastatic disease and it will be used as monotherapy for patients that had disease progression following endocrine therapy and prior chemotherapy. Patient has a diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence and will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# VIBERZI

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## Products Affected

- Viberzi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.                                      |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of irritable bowel syndrome with diarrhea. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |



# VITRAKVI

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## Products Affected

- Vitrakvi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has solid tumors that have all of the following characteristics: a confirmed neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, metastatic disease or where surgical resection is likely to result in severe morbidity, AND there are no satisfactory alternative treatments or disease has progressed following treatment. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# VIZIMPRO

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## Products Affected

- Vizimpro

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations. Vizimpro will be used as a first-line treatment. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | N/A  |

# VONJO

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## Products Affected

- Vonjo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF). Patient has a platelet count below 50 x 10 <sup>9</sup> /L. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | PLAN YEAR  |
| <b>Other Criteria</b>               | N/A  |

# VOSEVI

## Products Affected

- Vosevi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Information required for review: genotype, prior HCV treatments, cirrhosis status (including Child-Pugh class), desired treatment regimen, viral load, HIV status, liver transplant history. Requests will be reviewed against the most current edition of the American Association for the Study of Liver Diseases (AASLD) Infectious Diseases Society of America (IDSA) guidelines for Hepatitis C infection. Patients must be prescribed regimens recommended under these guidelines with the highest evidence rating in that category as of the date of the request. In cases where the request is for a lower evidence rated treatment, an explanation will be required as to why the higher rated regimen is not preferred. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 12 weeks  |
| <b>Other Criteria</b>               | N/A   |

# VOTRIENT

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## Products Affected

- Pazopanib Hydrochloride
- Votrient

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of advanced renal cell carcinoma or advanced soft tissue sarcoma. Patients with a diagnosis of soft tissue sarcoma must have received prior chemotherapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# WELIREG

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## Products Affected

- Welireg

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of von Hippel-Lindau (VHL) disease and requires therapy for associated renal cell carcinoma, central nervous system hemangioblastomas, or pancreatic neuroendocrine tumors (pNET) not requiring immediate surgery. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# XALKORI

## Products Affected

- Xalkori

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC) and the tumor is ROS1- or ALK-positive. Patient is a pediatric patient or a young adult with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive. Patient has a diagnosis of unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) that is ALK-positive. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# XELJANZ

## Products Affected

- Xeljanz

- Xeljanz Xr

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | Xeljanz tab/Xeljanz XR tab: Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Ankylosing spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. RA, PsA, AS (Initial): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Enbrel, Humira). Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine), azathioprine, or corticosteroids (eg, prednisone). Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Humira). Not used in combination with other Janus kinase (JAK) inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | RA, PJIA, AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. UC (initial): Prescribed by or in consultation with a gastroenterologist.  |

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Last Updated: June 2024



|                          |   |
|--------------------------|---|
| <b>Coverage Duration</b> | Plan year   |
| <b>Other Criteria</b>    | <p>Xeljanz: Polyarticular course juvenile idiopathic arthritis (PJIA) (Initial): Diagnosis of active polyarticular course juvenile idiopathic arthritis. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Enbrel, Humira). RA, PsA, AS, PJIA (Initial): Not used in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or potent immunosuppressants (eg, azathioprine, cyclosporine). RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. RA, PsA, AS, PJIA (reauth): Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (eg, azathioprine, cyclosporine). UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. Not used in combination with other JAK inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine).</p> |

# XERMELO

## Products Affected

- Xermelo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of carcinoid syndrome diarrhea. Patient will also be on a somatostatin analog (SSA) therapy (e.g., octreotide). Patient has had inadequate control on SSA therapy after a trial of at least 3 months. Patient has at least 4 bowel movements per day. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist or gastroenterologist.  |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# XGEVA

## Products Affected

- Xgeva

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Multiple Myeloma (MM)/Bone metastasis from solid tumors (BMST): One of the following: 1) Diagnosis of multiple myeloma OR 2) diagnosis of solid tumors (eg, breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer), AND documented evidence of one or more metastatic bone lesions. Giant cell tumor of bone (GCTB): Both of the following: 1) diagnosis of giant cell tumor of bone AND 2) One of the following: a) tumor is unresectable, OR b) surgical resection is likely to result in severe morbidity. Hypercalcemia of malignancy (HCM): Both of the following: 1) diagnosis of hypercalcemia of malignancy, AND 2) Trial and failure, contraindication, or intolerance to one intravenous bisphosphonate (eg, pamidronate, Zometa (zoledronic acid). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | GCTB, HCM: Prescribed by or in consultation with an oncologist   |
| <b>Coverage Duration</b>            | MM/BMST, GCTB: 12 mo. HCM: 2 mo.   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# XOLAIR

## Products Affected

- Xolair

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of moderate or persistent asthma with base inadequate control on either inhaled corticosteroids and long acting beta agonist or inhaled corticosteroids and long acting muscarinic antagonist, a diagnosis of chronic idiopathic urticaria who remained symptomatic after previous trials of H1 antihistamines, or a diagnosis of nasal polyps and will be used as add-on maintenance in patients with an inadequate response to nasal corticosteroids. Or patient has a diagnosis of an IgE-mediated food allergy and Xolair is being used for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. AND this will be used in conjunction with food allergen avoidance. |
| <b>Age Restrictions</b>             | Asthma age 6 and older, Chronic idiopathic Urticaria Age 12 and older, nasal polyps age 18 and older  |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# XOSPATA

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## Products Affected

- Xospata

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of relapsed or refractory acute myeloid leukemia (AML). Patient has a FMS-like tyrosine kinase 3 (FLT3) mutation. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# XPOVIO

## Products Affected

- Xpovio
- Xpovio 100 Mg Once Weekly
- Xpovio 40 Mg Once Weekly
- Xpovio 40 Mg Twice Weekly
- Xpovio 60 Mg Once Weekly
- Xpovio 60 Mg Twice Weekly
- Xpovio 80 Mg Once Weekly
- Xpovio 80 Mg Twice Weekly

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | Patient has a diagnosis of relapsed or refractory multiple myeloma (RRMM) and meet one of the following criteria: 1) received at least four prior therapies, disease must be refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody, and therapy must be used in combination with dexamethasone or 2) patient has received at least one prior therapy and it will be used in combination with bortezomib and dexamethasone. OR Patient has a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including arising from follicular lymphoma and must have tried at least 2 lines of systemic therapy. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan year  |
| Other Criteria               | N/A  |

# XTANDI

## Products Affected

- Xtandi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has a diagnosis of castration-resistant prostate cancer (CRPC) or metastatic castration-sensitive prostate cancer.   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan year  |
| <b>Other Criteria</b>               | For patients with metastatic, castration-resistant prostate cancer in patients who are not currently taking Xtandi, the patient must have had a trial with abiraterone (Zytiga) unless the patient is unable to try abiraterone. |

# YONSA

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## Products Affected

- Yonsa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has metastatic castration-resistant prostate cancer. Yonsa will be used in combination with methylprednisolone. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |



# YUFLYMA

## Products Affected

- Yuflyma 1-pen Kit
- Yuflyma 2-pen Kit
- Yuflyma 2-syringe Kit
- Yuflyma Cd/uc/hs Starter

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | <p>Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. PsO (Initial): Diagnosis of moderate to severe chronic PsO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week TF/C/I to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CAI) greater than 220. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), methotrexate. Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis.</p> |

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|                                |   |
|--------------------------------|---|
| <b>Age Restrictions</b>        | N/A   |
| <b>Prescriber Restrictions</b> | RA, AS, PJIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS (initial): Prescribed by or in consultation with a dermatologist. CD, UC (initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist. |
| <b>Coverage Duration</b>       | Plan Year   |

|                              |   |
|------------------------------|---|
| <p><b>Other Criteria</b></p> | <p>Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), aminosalicylate [eg, mesalamine, olsalazine, sulfasalazine]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Hidradenitis suppurativa (HS), Uveitis (Reauth): Patient demonstrates positive clinical response to therapy. Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. CD (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. UC (Reauth): For patients who initiated therapy within the past 12 weeks: Patient demonstrates clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on therapy for longer than 12 weeks: Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.</p> |
|------------------------------|---|

# ZEJULA

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## Products Affected

- Zejula

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of advanced or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. OR Patient has a diagnosis of of deleterious or suspected deleterious germline BRCA-mutated (gBRCAmut) recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# ZELBORAF

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## Products Affected

- Zelboraf

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis of unresectable or metastatic melanoma and patient has positive BRAF-V600E mutation OR patient has a diagnosis of Erdheim-Chester Disease (ECD) with BRAF V600E mutation. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# ZEPATIER

## Products Affected

- Zepatier

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Patient has moderate or severe hepatic impairment (Child-Pugh B or C).<br>Patient is on OATP1B1/3 inhibitors, strong inducers of CYP3A or efavirenz.   |
| <b>Required Medical Information</b> | Information required for review: genotype, prior treatments, cirrhosis status, desired treatment regimen, viral load, HIV status, liver transplant history, renal impairment status, NS5A polymorphism status. Requests will be reviewed against the most current edition of the American Association for the Study of Liver Diseases (AASLD) Infectious Diseases Society of America (IDSA) guidelines for Hepatitis C infection. Patients must be prescribed regimens recommended under these guidelines as of the date of the request. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 16 wks: G1a Tx-naive or PegIFN/RBV-exp with baseline NS5A or G4 PegIFN/RBV-exp 12 wks for others   |
| <b>Other Criteria</b>               | N/A  |

# ZOLINZA

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## Products Affected

- Zolinza

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of cutaneous T-cell lymphoma with progressive, persistent or recurrent disease. Patient has received at least two prior systemic therapies. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# ZTALMY

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## Products Affected

- Ztalmy

| <b>PA Criteria</b>                  | <b>Criteria Details</b>       |
|-------------------------------------|-------------------------------|
| <b>Indications</b>                  | All FDA-approved Indications. |
| <b>Off-Label Uses</b>               | N/A                           |
| <b>Exclusion Criteria</b>           | N/A                           |
| <b>Required Medical Information</b> | N/A                           |
| <b>Age Restrictions</b>             | N/A                           |
| <b>Prescriber Restrictions</b>      | N/A                           |
| <b>Coverage Duration</b>            | Plan Year                     |
| <b>Other Criteria</b>               | N/A                           |



# ZURZUVAE

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## Products Affected

- Zurzuvae

| <b>PA Criteria</b>                  | <b>Criteria Details</b>                      |
|-------------------------------------|--|
| <b>Indications</b>                  | Some FDA-approved Indications Only.          |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Treatment of postpartum depression in adults |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year                                    |
| <b>Other Criteria</b>               | N/A  |

# ZYDELIG

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## Products Affected

- Zydelig

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For relapsed chronic lymphocytic leukemia, Zydelig is used in combination with rituximab. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

# ZYKADIA

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## Products Affected

- Zykadia TABS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Patient has a diagnosis of metastatic non-small cell lung cancer and has anaplastic lymphoma kinase (ALK)-positive disease. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan year   |
| <b>Other Criteria</b>               | N/A   |

## PART B VERSUS PART D

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### Products Affected

- Abelcet
- Acetylcysteine INHALATION SOLN
- Acyclovir Sodium INJ 50MG/ML
- Adriamycin INJ 10MG, 2MG/ML, 50MG
- Albuterol Sulfate NEBU 0.083%, 0.63MG/3ML, 1.25MG/3ML, 2.5MG/0.5ML
- Aminosyn II INJ 107.6MEQ/L; 1490MG/100ML; 1527MG/100ML; 1050MG/100ML; 1107MG/100ML; 750MG/100ML; 450MG/100ML; 990MG/100ML; 1500MG/100ML; 1575MG/100ML; 258MG/100ML; 447MG/100ML; 1083MG/100ML; 795MG/100ML; 50MEQ/L; 600MG/100ML; 300MG/100ML; 405MG/100ML; 750MG/100ML, 71.8MEQ/L; 993MG/100ML; 1018MG/100ML; 700MG/100ML; 738MG/100ML; 500MG/100ML; 300MG/100ML; 660MG/100ML; 1000MG/100ML; 1050MG/100ML; 172MG/100ML; 298MG/100ML; 722MG/100ML; 530MG/100ML; 38MEQ/L; 400MG/100ML; 200MG/100ML; 270MG/100ML; 500MG/100ML
- Aminosyn-pf INJ 46MEQ/L; 698MG/100ML; 1227MG/100ML; 527MG/100ML; 820MG/100ML; 385MG/100ML; 312MG/100ML; 760MG/100ML; 1200MG/100ML; 677MG/100ML; 180MG/100ML; 427MG/100ML; 812MG/100ML; 495MG/100ML; 70MG/100ML; 512MG/100ML; 180MG/100ML; 44MG/100ML; 673MG/100ML
- Aminosyn-pf 7% INJ 32.5MEQ/L; 490MG/100ML; 861MG/100ML; 370MG/100ML; 576MG/100ML; 270MG/100ML; 220MG/100ML; 534MG/100ML; 831MG/100ML; 475MG/100ML; 125MG/100ML; 10.69GM/L; 300MG/100ML; 570MG/100ML; 70GM/L; 347MG/100ML; 50MG/100ML; 360MG/100ML; 125MG/100ML; 44MG/100ML; 452MG/100ML
- Amphotericin B INJ
- Amphotericin B Liposome
- Aprepitant CAPS
- Arformoterol Tartrate
- Astagraf XL
- Azathioprine TABS
- Bleomycin Sulfate INJ
- Budesonide SUSP
- Clinimix 4.25%/dextrose 10%
- Clinimix 4.25%/dextrose 5%
- Clinimix 5%/dextrose 15%
- Clinimix 5%/dextrose 20%
- Clinimix 6/5
- Clinimix 8/10
- Clinimix E 2.75%/dextrose 5% INJ 570MG/100ML; 316MG/100ML; 33MG/100ML; 5GM/100ML; 515MG/100ML; 132MG/100ML; 165MG/100ML; 201MG/100ML; 159MG/100ML; 51MG/100ML; 110MG/100ML; 454MG/100ML; 154MG/100ML; 261MG/100ML; 187MG/100ML; 138MG/100ML; 217MG/100ML; 112MG/100ML; 116MG/100ML; 50MG/100ML; 11MG/100ML; 160MG/100ML
- Clinimix E 4.25%/dextrose 10%
- Clinimix E 4.25%/dextrose 5%
- Clinimix E 5%/dextrose 15%
- Clinimix E 5%/dextrose 20%
- Clinimix E 8/10

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- Clinisol Sf 15%
- Clinolipid
- Cromolyn Sodium NEBU
- Cyclophosphamide CAPS
- Cyclophosphamide TABS
- Cyclosporine CAPS
- Cyclosporine Modified
- Cytarabine INJ 100MG/ML, 20MG/ML
- Cytarabine Aqueous
- Doxorubicin Hcl INJ 2MG/ML, 50MG
- Doxorubicin Hydrochloride INJ 10MG
- Dronabinol
- Duopa
- Emend SUSR
- Engerix-b
- Envarsus Xr
- Everolimus TABS 0.25MG, 0.5MG, 0.75MG, 1MG
- Fluorouracil INJ 1GM/20ML, 2.5GM/50ML, 500MG/10ML, 5GM/100ML
- Formoterol Fumarate NEBU
- Freamine Hbc 6.9%
- Freamine III INJ 89MEQ/L; 710MG/100ML; 950MG/100ML; 3MEQ/L; 24MG/100ML; 1400MG/100ML; 280MG/100ML; 690MG/100ML; 910MG/100ML; 730MG/100ML; 530MG/100ML; 560MG/100ML; 10MMOLE/L; 120MG/100ML; 1120MG/100ML; 590MG/100ML; 10MEQ/L; 400MG/100ML; 150MG/100ML; 660MG/100ML
- Gengraf CAPS 100MG, 25MG
- Gengraf SOLN
- Granisetron Hydrochloride TABS
- Hepatamine INJ 62MEQ/L; 770MG/100ML; 600MG/100ML; 3MEQ/L; 20MG/100ML; 900MG/100ML; 240MG/100ML; 900MG/100ML; 1100MG/100ML; 610MG/100ML; 100MG/100ML; 100MG/100ML; 115MG/100ML; 800MG/100ML; 500MG/100ML; 450MG/100ML; 66MG/100ML; 840MG/100ML
- Heplisav-b
- Imovax Rabies (h.d.c.v.)
- Intralipid INJ 20GM/100ML, 30GM/100ML
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Levalbuterol NEBU
- Levalbuterol Hcl NEBU
- Levalbuterol Hydrochloride NEBU 0.63MG/3ML
- Mycophenolate Mofetil CAPS
- Mycophenolate Mofetil SUSR
- Mycophenolate Mofetil TABS
- Mycophenolic Acid Dr
- Nephramine
- Nutrilipid
- Ondansetron Hcl SOLN
- Ondansetron Hcl TABS 24MG
- Ondansetron Hydrochloride TABS
- Ondansetron Odt
- Pentamidine Isethionate INHALATION SOLR
- Plenamine INJ 147.4MEQ/L; 2.17GM/100ML; 1.47GM/100ML; 434MG/100ML; 749MG/100ML; 1.04GM/100ML; 894MG/100ML; 749MG/100ML; 1.04GM/100ML; 1.18GM/100ML; 749MG/100ML; 1.04GM/100ML; 894MG/100ML; 592MG/100ML; 749MG/100ML; 250MG/100ML; 39MG/100ML; 960MG/100ML
- Prehevbrio

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Last Updated: June 2024

- Premasol INJ 52MEQ/L; 1760MG/100ML; 880MG/100ML; 34MEQ/L; 1760MG/100ML; 372MG/100ML; 406MG/100ML; 526MG/100ML; 492MG/100ML; 492MG/100ML; 526MG/100ML; 356MG/100ML; 356MG/100ML; 390MG/100ML; 34MG/100ML; 152MG/100ML
- Procalamine
- Prograf PACK
- Prosol
- Pulmozyme SOLN 2.5MG/2.5ML
- Rabavert
- Recombivax Hb
- Sandimmune SOLN
- Sirolimus SOLN
- Sirolimus TABS
- Synthamin 17
- Tacrolimus CAPS
- Tobramycin NEBU
- Travasol INJ 52MEQ/L; 1760MG/100ML; 880MG/100ML; 34MEQ/L; 1760MG/100ML; 372MG/100ML; 406MG/100ML; 526MG/100ML; 492MG/100ML; 526MG/100ML; 492MG/100ML; 356MG/100ML; 500MG/100ML; 356MG/100ML; 390MG/100ML; 34MG/100ML; 152MG/100ML
- Trophamine INJ 0.54GM/100ML; 1.2GM/100ML; 0.32GM/100ML; 0; 0; 0.5GM/100ML; 0.36GM/100ML; 0.48GM/100ML; 0.82GM/100ML; 1.4GM/100ML; 1.2GM/100ML; 0.34GM/100ML; 0.48GM/100ML; 0.68GM/100ML; 0.38GM/100ML; 5MEQ/L; 0.025GM/100ML; 0.42GM/100ML; 0.2GM/100ML; 0.24GM/100ML; 0.78GM/100ML
- Varubi TBPK
- Vinblastine Sulfate INJ 1MG/ML
- Vincasar Pfs
- Vincristine Sulfate INJ
- Voriconazole INJ

## Details

This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

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