## Summary of Utilization Management (UM) Program Changes

## June 2021

| Brand Name | Generic Name | Utilization Update Summary | Type | Effective Date |
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| *Zokinvy* | lonafarnib | Indicated in patients 12 months of age and older with a body surface area of 0.39 $m^2$ and above:<br>**1.** To reduce risk of mortality in Hutchinson-Gilford Progeria Syndrome **and**<br>**2.** For treatment of processing-deficient Progeroid Laminopathies with either: Heterozygous LMNA mutation with progerin-like protein accumulation or Homozygous or compound heterozygous ZMPSTE24 mutations.<br><br>Initial criteria requires:<br>**1.** One of the following:<br>**a.** Diagnosis of Hutchinson-Gilford Progeria Syndrome, **OR**<br>**b.** For treatment of processing-deficient Progeroid Laminopathies with one of the following lab tests:<br>**i)** Heterozygous LMNA mutation with progerin-like protein accumulation, **OR**<br>**ii)** Homozygous or compound heterozygous ZMPSTE24 mutations;<br>**2.** Patient is 12 months of age or older; and<br>**3.** Patient has a body surface area of 0.39 $m^2$ and above | New | 8/15/2021 |
| *Oxlumo* | lumasiran | Treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels in pediatric and adult patients.<br><br>Initial criteria requires:<br>1) Diagnosis of primary hyperoxaluria type 1 (PH1);<br>2) Diagnosis has been confirmed by **both** of the following:<br>**a)** Elevated urinary oxalate excretion **or** elevated plasma oxalate concentration, **and**<br>**b)** Genetic testing demonstrating a mutation in the alanine: glyoxylate aminotransferase (AGXT) gene;<br>3) Patient has not received a liver transplant; **and**<br>4) Prescribed by: nephrologist, urologist, geneticist, **or** specialist with expertise in the treatment of PH1 | New | 8/15/2021 |
| *Orladeyo*<br>*Ruconest*<br>*Berinert*<br>*Cinryze*<br>*Haegarda*<br>*Kalbitor*<br>*Firazyr*<br>*Takhzyro*<br>*In Hereditary Angioedema Agents* | berotralstat<br>C1 esterase inhibitor<br>C1 esterase inhibitor<br>C1 esterase inhibitor<br>C1 esterase inhibitor<br>ecallantide<br>icatibant<br>lanadelumab-flyo | Orladeyo is indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years of age and older. It is new to the market. Orladeyo is a plasma kallikrein inhibitor and is the first orally administered non-steroidal option for preventing HAE attacks. Orladeyo will be added to the HAE Agents PA guidelines.<br><br>Initial criteria requires:<br>**1.** Diagnosis of hereditary angioedema (HAE);<br>**2.** Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following: | Update | 8/15/2021 |

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| | | **a)** C1-INH antigenic level below the lower limit of normal, **OR**<br>**b)** C1-INH functional level below the lower limit of normal;<br>**3.** For prophylaxis against HAE attacks; and<br>**4.** Prescribed by or in consultation with one of the following: immunologist or allergist<br>The other drugs in this guideline will now require the diagnosis as noted in 2 above. Rheumatologist has been removed as an approved specialist to prescribe these drugs. | | |
| *Danyelza* | naxitamib-gqgk | Reauthorization criteria have been removed. The drug should only be used for a maximum of 5 cycles. | Update | 8/15/2021 |
| *Eysuvis* | loteprednol | Indicated for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease.<br><br>Initial criteria requires:<br>**1.** Diagnosis of dry eye disease;<br>**2.** Trial and failure for a minimum 14 days duration of therapy, contraindication, or intolerance to **one** of the following:<br>**a)** 0.5% loteprednol suspension, or<br>**b)** 0.1% fluorometholone suspension;<br>**3.** Prescribed by ophthalmologist or optometrist | New | 8/15/2021 |
| *Winlevi* | clascoterone | Androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.<br><br>Initial criteria requires:<br>**1.** Diagnosis of acne vulgaris (i.e., acne);<br>**2.** Patient is 12 years of age or older;<br>**3.** Trial and inadequate response (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to **three** of the following:<br>**a)** generic adapalene (cream, gel, lotion),<br>**b)** generic topical tretinoin or tretinoin microsphere,<br>**c)** generic tazarotene cream,<br>**d)** generic single-agent topical clindamycin product,<br>**e)** generic dapsone gel | New | 8/15/2021 |
| *Nyvepria*<br>*Udenyca*<br>*Ziextenzo*<br>*In Colony-Stimulating Factors* | pegfilgrastim-apgf<br>pegfilgrastim-cbqv<br>pegfilgrastim-bmez | Added to the guideline with the same requirements of other pegfilgrastim products for the treatment of: febrile neutropenia (prevention); treatment of high-risk febrile neutropenia; or acute radiation syndrome. | Update | 8/15/2021 |
| *Riabni in Rituximab Products* | rituximab-arrx | New biosimilar to Rituxan. Indicated for Non-Hodgkin's Lymphoma (NHL), Chronic Lymphocytic Leukemia (CLL), Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA).<br><br>Riabni will be added into the Rituximab PA guidelines and existing criteria will apply. This includes a trial and failure of Ruxience (also rituximab) first. | Update | 8/15/2021 |
| *Benlysta* | belimumab | Treatment of adult patients with active lupus nephritis who are receiving standard therapy. Previously only approved for patients aged 5 years | Update | 8/15/2021 |

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| | | and older with active, autoantibody-positive systemic lupus erythematosus (SLE) who are receiving standard therapy.<br><br>Criteria will be updated due to this new indication. Initial criteria requires:<br>**1.** Diagnosis of active lupus nephritis;<br>**2.** Currently receiving standard of care treatment for active lupus nephritis (e.g., corticosteroids [e.g., prednisone] with mycophenolate or cyclophosphamide); **and**<br>**3.** Prescribed by nephrologist or rheumatologist. | | |
| *Hetlioz*<br>*Hetlioz LQ* | tasimelteon | Treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 16 years of age and older. Also indicated for Non-24-Hour Sleep-Wake Disorder (Non-24).<br><br>Initial criteria for new indication requires:<br>1) Diagnosis of Smith-Magenis Syndrome (SMS);<br>2) Patient is 16 years of age or older;<br>3) Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent night-time waking and early waking); and<br>4) Prescribed by a specialist in sleep disorders<br><br>Existing Non-24-Hour Sleep-Wake Disorder criteria section update to indicate it only applies to the Hetlioz capsule formulation.<br><br>New **oral suspension (liquid) formulation** has been approved. Indicated to treat nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in pediatric patients 3 to 15 years of age.<br><br>Initial criteria requires:<br>1) Diagnosis of Smith-Magenis Syndrome (SMS);<br>2) Patient is 3 through 15 years of age;<br>3) Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent night-time waking and early waking); and<br>4) Prescribed by a specialist in sleep disorders | Update | 8/15/2021 |
| *Kineret* | anakinra | Treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA). Kineret is also approved for active rheumatoid arthritis and Cryopyrin-Associated Periodic Syndromes (CAPS).<br><br>Initial criteria for new indication requires:<br>**1.** Diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA). | Update | 8/15/2021 |
| *Arcalyst* | rilonacept | Maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing at least 10 kg. Arcalyst is also approved for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS).<br><br>Criteria update for new indication requires: | Update | 8/15/2021 |

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| | | **1.** Diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA);<br>**2.** Patient weighs at least 10 kg; and<br>**3.** Patient is currently in remission (e.g., no fever, skin rash, and bone pain; no x-ray evidence of active bone lesions; C-reactive protein [CRP] less than 5 mg/L). | | |
| *Trikafta* | elexacaftor-tezacaftor-ivacaftor; ivacaftor | Trikafta was previously only approved for patients with at least one F508del mutation and is now approved for 177 additional mutations.<br><br>Criteria update expanded indication to include an allowance for patients having at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive based on in vitro data (previously only allowed for a F508del mutation). | Update | 8/15/2021 |
| *Kalydeco* | ivacaftor | Label update to include an additional 59 responsive mutations.<br><br>Criteria update allows for at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data. | Update | 8/15/2021 |
| *Symdeko* | tezacaftor-ivacaftor; ivacaftor | Label update to include an additional 127 responsive mutations.<br><br>Criteria update to allow for at least one mutation on in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence. | Update | 8/15/2021 |
| *Tagrisso* | osimertinib | Adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.<br><br>Also approved for the:<br>**1.** First-line treatment of adult patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test, and<br>**2.** Treatment of adult patients with metastatic EGFR T790M mutation-positive NSCLC, as detected by an FDA-approved test, whose disease has progressed on or after EGFR tyrosine kinase inhibitor therapy.<br><br>Initial criteria requires:<br>**1.** Diagnosis of non-small cell lung cancer (NSCLC);<br>**2.** Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA);<br>**3. Both** of the following:<br>**a)** Patient is receiving as adjuvant therapy, **and** | Update | 8/15/2021 |

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| | | **b)** Patient has had a complete surgical removal of the primary non-small cell lung cancer (NSCLC) tumor; and<br>**4.** Prescribed by an oncologist | | |
| *Xolair* | omalizumab | Add-on maintenance treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids. Xolair is also approved for asthma and chronic idiopathic urticaria.<br><br>Initial criteria for new indication requires:<br>**1.** Diagnosis of nasal polyps;<br>**2.** Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (for example, fluticasone, mometasone);<br>**3.** Use in combination with another agent for nasal polyps (for example, an intranasal corticosteroid);<br>**4.** Prescribed by an allergist/immunologist, otolaryngologist, or pulmonologist.<br><br>For all indications, approval for continuation of therapy is available. | Update | 8/15/2021 |
| *Xpovio* | selinexor | In combination with bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. (Xpovio is also approved for use in combination with dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody).<br><br>Criteria for new indication requires:<br>**1.** Diagnosis of multiple myeloma;<br>**2.** Patient has received at least one prior therapy;<br>**3.** Used in combination with bortezomib and dexamethasone; and<br>**4.** Prescribed by an oncologist/hematologist | Update | 8/15/2021 |
| *Zykadia* | ceritinib | For patients new to the medication, criteria will require **one** of the following:<br>**1.** Patient has had disease progression on, contraindication or intolerance to, or is not a candidate for one of the following: Alecensa (alectinib) or Alunbrig (brugatinib) | Update | 8/15/2021 |
| *Xalkori* | crizotinib | Indicated for the treatment of pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive.<br><br>Criteria for new indication requires:<br>**1.** Diagnosis of systemic anaplastic large cell lymphoma (ALCL);<br>**2.** Disease is one of the following: relapsed or refractory; | Update | 8/15/2021 |

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| | | **3.** Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA); and<br>**4.** Prescribed by oncologist/hematologist<br><br>For the non-small cell lung cancer indication, for patients who are new to the medication, criteria will require:<br>**1.** Patient has had disease progression on, contraindication or intolerance to, or is not a candidate for one of the following: Alecensa (alectinib) or Alunbrig (brugatinib). | | |
| *Zortress* | everolimus | Retirement of guideline; prior authorization will no longer be needed | Update | 8/15/2021 |
| *Nulojix in Injectable Immunosuppressants* | belatacept | Retirement of guideline; prior authorization will no longer be needed | Update | 8/15/2021 |
| *Topical Antifungals* | | For the indication of toenail onychomycosis, revised criteria of mild to moderate disease involving at least one "great" toenail to "target" toenail to align with product information. Clarified that the required trial for Jublia is "brand" Kerydin. | Update | 8/15/2021 |