Summary of Utilization Management (UM) Program Changes

April 2021

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
Gavreto	pralsetinib	Indicated for the treatment of adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test. Initial criteria requires: **1)** Diagnosis of non-small cell lung cancer; **2)** Presence of rearranged during transfection (RET) gene fusion-positive tumor(s); and **3)** Prescribed by an oncologist.	New	6/5/2021
Kesimpta (in Multiple Sclerosis)	ofatumumab	Treatment in adults: Relapsing forms of multiple sclerosis (MS) including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. Initial criteria requires: **1)** Diagnosis of a relapsing form of multiple sclerosis (MS) **2)** One of the following: **a)** Failure after a trial of at least 4 weeks of one or intolerance to two of the following: Aubagio, Avonex, Copaxone/Glatopa, Gilenya, Plegridy, or Tecfidera **OR** **b)** continuation of prior therapy **3)** Not used in combination with another disease-modifying therapy for MS or B-cell targeted therapy **4)** Prescribed by neurologist.	Update	6/5/2021
Onureg	azacitidine	Treatment of adult acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy. Initial criteria requires: **1)** Diagnosis of acute myeloid leukemia (AML); **2)** Previous treatment with an intensive induction chemotherapy regimen (such as, cytarabine + daunorubicin, cytarabine + idarubicin, etc.); **3)** Patient has achieved **one** of the following: first complete remission (CR) or complete remission with incomplete blood count recovery (CRi); **4)** Patient is not able to complete intensive curative therapy; and **5)** Prescribed by a hematologist/oncologist.	New	6/5/2021
Cystadrops (in Cystaran, Cystadrops guideline)	cysteamine	New formulation indicated for treatment of corneal cystine crystal deposits in adults and children with cystinosis. Cystadrops will be added to the existing Cystaran guideline. Initial criteria requires: **1)** Diagnosis of cystinosis	Update	6/5/2021

		2) Diagnosis is confirmed by elevated leukocyte cystine levels (LCL), genetic analysis of the CTNS gene or corneal cystine crystal accumulation **3)** Patient is concomitantly receiving treatment with oral cysteamine.		
Ferriprox	deferiprone	Trial and failure OR history of contraindication or intolerance to one chelation therapy (such as deferasirox).	Update	6/5/2021
Kalydeco	ivacaftor	The drug is now approved to be used in patients 4 months of age and older. No change to the criteria**.**	Update	6/5/2021
Julia *Kerydin*	Efinaconazole tavaborole	Initial criteria requires: **1)** Diagnosis of onychomycosis of the toenail(s); **2)** Patient does not have dermatophytomas or nail matrix involvement; **3)** Diagnosis of toenail onychomycosis has been confirmed by **ONE** of the following: **a)** Positive potassium hydroxide (KOH) preparation, **b)** Culture, **c)** Histology; **4)** Patient has mild to moderate disease involving at least one great toenail; **5)** Treatment is requested due to a documented medical condition and not for cosmetic purposes (e.g. patients with history of cellulitis of the lower extremity, patients with diabetes who have additional risk factors for cellulitis of lower extremity, patients who experience pain/discomfort associated with the infected nail); **6)** One of the following: **a)** History of failure or contraindication, **or** intolerance to 12 weeks of treatment with ciclopirox (document date and duration of trial), OR **b)** Patient is 6 to 12 years of age; **7)** History of failure, contraindication, or intolerance to 12 weeks of treatment with **ONE** of the following oral antifungal agents (document date and duration of trial): itraconazole, terbinafine, griseofulvin.	New	6/5/2021
Copiktra	duvelisib	Calquence and Venclexta were added as options for trial and failure for Chronic Lymphocytic Leukemia and Small Lymphocytic Leukemia.	Update	6/5/2021
Reditrex (in Methotrexate Autoinjectors)	methotrexate	New subcutaneous syringe formulation Indicated for: **1)** Management of patients with severe, active rheumatoid arthritis (RA) and polyarticular juvenile idiopathic arthritis (pJIA), who are intolerant of or had an inadequate response to first-line therapy, and **2)** Symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy. Initial criteria requires: **1)** Diagnosis of severe rheumatoid arthritis or polyarticular juvenile idiopathic arthritis **2)** Prescribed by a rheumatologist **OR** **3)** Diagnosis of severe psoriasis **4)** Prescribed by a dermatologist **AND** **5)** Trail and failure of oral methotrexate.	Update	6/5/2021

Banzel	rufinamide	A new generic available. Approval will require a trial and inadequate response to a generic anticonvulsant that is on formulary.	Update	6/5/2021
Nucala	mepolizumab	New indication: Treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable blood-system secondary cause. Initial criteria requires: **1)** Diagnosis of hypereosinophilic syndrome (HES); **2)** Patient has been diagnosed for at least 6 months; **3)** Verification that other nonhematologic secondary causes have been ruled out (such as, drug hypersensitivity, parasitic worm infection, HIV infection, non-hematologic malignancy); **4)** Confirmation that the patient is Fip1-like1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFRA)-negative; **5)** Confirmation that patient has uncontrolled HES defined as a history of 2 or more flares within the past 12 months **AND** pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter; **6)** Trial and failure to either corticosteroid therapy (such as, prednisone) or cytotoxic/immunosuppressive therapy (such as, hydroxyurea, cyclosporine, imatinib); and **7)** Prescribed by an allergist/immunologist or hematologist.	Update	6/5/2021
Wakix	pitolisant	New indication for treatment of cataplexy in adult patients with narcolepsy. Previously indicated for the treatment of excessive daytime sleepiness in adult patients with narcolepsy. Initial criteria requires: **1)** Diagnosis of narcolepsy as confirmed by sleep a sleep study; **2)** Symptoms of cataplexy are present; **3)** Symptoms of excessive daytime sleepiness (such as, irrepressible need to sleep or daytime lapses into sleep) are present; and **4)** Prescribed by neurologist, psychiatrist, or sleep medicine specialist. Updates to existing indication to differentiate from the new narcolepsy with cataplexy indication. For**:** "Narcolepsy without Cataplexy" Initial criteria requires: **1)** Diagnosis of narcolepsy as confirmed by a sleep study; **2)** Adding "symptoms of cataplexy are absent“ **3)** Adding "symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present“ **4)** Adding " Prescribed by a neurologist, psychiatrist, or sleep medicine specialist.”	Update	6/5/2021

Simponi Aria	golimumab	New indication for the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older. Initial criteria requires: **1)** Diagnosis of moderate to severely active pJIA; **2)** Prescribed by a rheumatologist; **and** **3)** One of the following: Trial and failure, contraindication, or intolerance to one of the following non-biologic disease-modifying antirheumatic drugs (DMARDs): Arava (leflunomide) or methotrexate (Rheumatrex/Trexall).	Update	6/5/2021
Xeljanz	tofacitinib	New indication for treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older. A new 1 mg/mL oral solution has also been approved for this pediatric population. Criteria for this new indication. Initial criteria requires: **1)** Diagnosis of active polyarticular course juvenile idiopathic arthritis; **2)** Prescribed by a rheumatologist; **3)** Trial and failure to **one** of the following non-biologic disease-modifying antirheumatic drugs (DMARDs): Arava (leflunomide) or methotrexate(Rheumatrex/Trexall); **4)** Trial and failure to Humira (adalimumab), or attestation demonstrating a trial may be inappropriate*, or documented needle-phobia, or for continuation of prior therapy; ***** Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor. **5)** Patient is not receiving Xeljanz in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine).	Update	6/5/2021
Enbrel	etanercept	Now that Xeljanz is approved for PJIA, it will be added to the required drug trials before approval of Enbrel. **Criteria**: Requires trial and failure of **all** of the following: Humira, Actemra, Orencia, and Xeljanz, or allow for continuation of therapy. **Additionally:** "attestation demonstrating a trial may be inappropriate" will be added to the Humira step along with verbiage in the notes section stating, "Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.	Update	6/5/2021
Orencia	abatacept	For the PJIA indication**:** verbiage added to notes section of guideline to indicate that if a total of two TNF inhibitors have already been tried in the past, then the patient should not be made to try a third TNF inhibitor. No changes to clinical criteria.	Update	6/5/2021
Apokyn, Kynmobi (in Apomorphine Products)	apomorphine	Updates to simplify criteria: **1)** To align with the prescription label, criteria simplified to read "Patient is experiencing intermittent OFF episodes" (instead of acute	Update	6/5/2021

		intermittent hypomobility with the definition of off episodes) **2)** Criteria that states "Used in combination with other medications for the treatment of Parkinson's disease" will be removed. Replaced with both of the following: - Patient is receiving drug in combination with carbidopa/levodopa at a maximally tolerated dose or Patient has a contraindication or intolerance to carbidopa/levodopa **AND** - Trial and failure, contraindication or intolerance to two of the following: MAO-B Inhibitor (such as, rasagiline, selegiline), Dopamine Agonist (such as, pramipexole, ropinirole), COMT Inhibitor (such as, entacapone).		
Botox	onabotulinumtoxinA	**1)** Criteria language will be updated to remove reference to migraine headache days: "Patient has greater than or equal to 15 [*migraine* was removed] headache days per month, of which at least 8 must be migraine days for at least 3 months" **2)** The specialist prescriber requirement will be updated to include the option of a headache specialist.	Update	6/5/2021
Aimovig *Emgality* *Ajovy* *Vyepti* *Nurtec* *Ubrelvy (in CGRP Inhibitors)*		The specialist prescriber requirement will be updated to include the option of a headache specialist.	Update	6/5/2021
Reyvow	lasmiditan	The specialist prescriber requirement will be updated to include the option of a headache specialist.	Update	6/5/2021
Migranal *DHE 45 (in Dihydroergotamine)*	dihydroergotamine	The specialist prescriber requirement will be updated to include the option of a headache specialist.	Update	6/5/2021
Fintepla		Initial criteria now requires**:** allow for continuation of therapy, **OR** require trial of **both** of the following: **a)** valproic acid OR clobazam, **and** **b)** One of the following: Diacomit (stiripentol), Epidiolex (cannabidiol), lamotrigine, topiramate, zonisamide, levetiracetam, or Briviact (brivaracetam).	Update	6/5/2021
Esbriet *Ofev (in Interstitial Lung Disease Agents)*	pirfenidone nintedanib	**Removal** of criteria that prohibits use in combination with each other.	Update	6/5/2021
Avsola (in Infliximab Products)	Infliximab	For approval of Remicade**:** Requires a trial of **2** of the following: Avsola, Inflectra, Renflexis [all are infliximab products].	Update	6/5/2021
Sandostain *Mycapssa (in Octreotide Products)*	octreotide	**Brand Sandostatin**: Require trial and failure of generic octreotide. **Mycapssa:** Require patient has responded to and tolerated generic octreotide or lanreotide.	Update	6/5/2021