Summary of Utilization Management (UM) Program Changes

October 2023

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
Joenja	leniolisib	For the treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in adult and pediatric patients 12 years of age and older. Initial criteria requires: 1) Diagnosis of activated phosphoinositide 3-kinase delta syndrome (APDS); 2) Molecular genetic testing confirms mutations in the PIK3CD or PIK3R1 gene; 3) Patient is 12 years of age or older; 4) Patient weighs greater than or equal to 45kg; 5) Both of the following: a) Presence of nodal and/or extranodal proliferation (e.g., lymphadenopathy, splenomegaly, hepatomegaly) b) Presence of other clinical findings and manifestations consistent with APDS (e.g., recurrent sino-pulmonary infections, bronchiectasis, enteropathy); 6) Trial and failure, contraindication, or intolerance to at least one standard of care treatment for APDS (e.g., Immunoglobulin replacement therapy, antimicrobial prophylaxis [e.g., azithromycin, bactrim], rituximab, tacrolimus, etc.); 7) Prescribed by or in consultation with one of the following: a) Hematologist or b) Immunologist	New	12/15/2023
Nocdurna	desmopressin	For the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void. For an initial approval duration of 3 months, criteria requires: 1) Diagnosis of nocturia due to nocturnal polyuria; 2) Nighttime urine production exceeds one-third of the 24-hour urine production; 3) Patient wakes at least twice per night on a reoccurring basis to void; 4) Initial serum sodium level prior to initiating therapy is within normal limits of the normal laboratory reference range; 5) One of the following: a) Underlying causes of nocturia have been ruled out (e.g., overactive bladder, benign prostatic hyperplasia (BPH), Parkinson's disease, excessive bedtime fluid intake) OR	New	1/1/2024

		b) Underlying medical causes of nocturia are treated prior to initiating therapy (e.g., use of alpha-adrenergic blockers or 5-alpha reductase inhibitors for BPH, vaginal estrogens for vaginal atrophy)		
Trikafta	elexacaftor / tezacaftor / ivacaftor	Expanded indication: Treatment of cystic fibrosis in patients aged 2 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive. The age for this indication has been lowered from 6 years and older to 2 years and older.	Update	12/15/2023
Zavzpret *Qulipta* *Nurtec ODT* *Ubrelvy in CGRP Inhibitors*	zavegepant atogepant rimegepant ubrogepant	Zavzpret: New intranasal formulation. Indicated for the acute treatment of migraine with or without aura in adults. For an initial approval duration of 3 months, criteria requires: 1) Diagnosis of migraine with or without aura; 2) Will be used for the acute treatment of migraine; 3) Patient is 18 years of age or older; 4) One of the following: a) Trial and failure or intolerance to two triptan(s) (e.g., eletriptan, rizatriptan, sumatriptan) b) Contraindication to all triptans; 5) [Commercial] Trial and failure, contraindication or intolerance to one of the following: a) Ubrelvy OR b) Nurtec ODT 6) If patient has 4 or more headache days per month, patient must be currently treated with one of the following: a) Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications b) Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications c) A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications d) Atacand (candesartan) unless there is a contraindication or intolerance to this medication e) Generic lisinopril unless there is a contraindication or intolerance to this medication	Update	12/15/2023

		7) Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines Qulipta: has an FDA indication for preventive treatment of migraines. Additional criteria for prevention of chronic migraines will require a diagnosis, at least 15 headache days per month, with 8 or more being migraines per month, over at least 3 months. Any offending medications that can cause medication overuse headaches have been discontinued. Nurtec ODT, Ubrelvy: For acute treatment of migraine indication, the following criteria updates will be made: - Remove initial criterion that requires "Patient has fewer than 15 headache days per month." - Criteria that requires "medication will not be used in combination with another oral CGRP inhibitor" will be updated to state "medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines." - ACE inhibitor (i.e., lisinopril) will be added as an additional option for prophylactic therapy if patient has 4 or more headache days per month. All drugs: The requirement for a specialist prescriber has been removed.		
Cuvrior in Copper Chelating Agents	trientine tetrahydrochloride	New oral tablet formulation indicated for the treatment of adult patients with stable Wilson's disease who are de-coppered and tolerant to penicillamine. Cuvrior will be added to guideline to mirror existing Syprine (trientine) criteria.	Update	12/15/2023
Alecensia *Alunbrig* *Ibrance* *Kisqali/Kisqali Femara Co-pack* *Lorbrena* *Lynparza* *Ninlaro* *Pomalyst* *Rubraca* *Talzenna* *Verzenio* *Xpovio* *Votrient* *Zejula*	alectinib brigatinib palbociclib ribociclib; ribociclib/letrozole lorlatinib olaparib ixazomib pomalidomide rucaparib talazoparib abemaciclib selinexor pazopanib niraparib	To simplify the guidelines for these oral oncology drugs, criteria below will be removed, as applicable. These changes are also supported by national cancer treatment guidelines. If applicable, the following criteria were removed: - Confirmation of disease severity (e.g., recurrent, metastatic) - Confirmation of disease genetic status - Requested drug is to be used in combination another agent or therapy (e.g., chemotherapy, radiotherapy, steroids, etc.)	Update	12/15/2023

		- Requested drug is to be used after trial and failure of other treatment option or after trial of prior line therapies unless preferred alternatives exist due to formulary strategy Xpovio: use for Multiple Myeloma and diffuse Large B cell Lymphoma will be simplified to require the diagnosis and treatment by an oncologist. Zejula: criteria will no longer require information on disease severity, genetic mutation, and maintenance stage of treatment.		
Mavyret	glecaprevir/pibrentasvir	Removed HIV coinfection criteria since the guidelines no longer list HIV as a contraindication to the simplified treatment approach.	Update	12/15/2023
Nexavar	sorafenib	Updated renal cell carcinoma criteria to include "advanced" renal cell carcinoma to align with FDA label information. Off-label use of the drug is removed (and a request would be reviewed under a general guideline).	Update	12/15/2023