Summary of Utilization Management (UM) Program Changes

December 2020

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
Qinlock	ripretinib	Indicated for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib (eg, Gleevec). Initial criteria requires: 1) Diagnosis of gastrointestinal stromal tumor (GIST); 2) Disease is advanced; 3) Patient has received prior treatment with three or more kinase inhibitors (e.g., sunitinib, regorafenib), one of which must include imatinib; and 4) Prescribed by an oncologist.	New	2/15/2021
Retevmo	selpercatinib	Retevmo is indicated for the treatment of: (1) Adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC); (2) Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy; and (3) Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). Initial criteria will require the following: Lung Cancer: 1) Diagnosis of metastatic non-small cell lung cancer; 2) Disease has presence of RET gene fusion-positive tumor(s); and 3) Prescribed by an oncologist. Medullary Thyroid Cancer:	New	2/15/2021

		1) Diagnosis of medullary thyroid cancer (MTC); 2) Disease is advanced or metastatic; 3) Disease has presence of RET gene mutation tumors(s); 4) Disease requires treatment with systemic therapy; and 5) Prescribed by an oncologist. Thyroid Cancer: 1) Diagnosis of thyroid cancer; 2) Disease is advanced or metastatic; 3) Disease has presence of RET gene fusion-positive tumor(s); 4) Disease requires treatment with systemic therapy; 5) One of the following: a) Patient did not respond adequately to radioactive iodine, or b) Radioactive iodine therapy is not appropriate; and 6) Prescribed by an oncologist or endocrinologist.		
Tabrecta	capmatinib	Indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test. Initial criteria will require: 1) Diagnosis of non-small cell lung cancer; 2) Disease is one of the following: recurrent, advanced, or metastatic; 3) Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA); and 4) Prescribed by an oncologist.	New	2/15/2021
Zeposia (in Multiple Sclerosis)	ozanimod	Zeposia is a new product approved for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated	New	2/15/2021

		syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Initial criteria requires: 1) Diagnosis of a relapsing form of MS (e.g., relapsing-remitting MS, secondary-progressive MS with relapses); 2) One of the following: a) For continuation of therapy, or b) Failure after a trial of at least 4 weeks, contraindication, or intolerance to at least two of the following disease-modifying therapies for MS: Aubagio, Avonex, Copaxone/Glatopa, Extavia, Gilenya, Plegridy, Tecfidera 3) Prescribed by a neurologist.		
Avsola	infliximab	Avsola is the 4th biosimilar approved for Remicade. Indicated for Crohn's disease (CD), pediatric CD, ulcerative colitis (UC), pediatric UC, rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS) and plaque psoriasis (PsO). Avsola will be added to existing Infliximab guideline and the criteria will mirror those of other non-preferred infliximab products. For approval of the Avsola product, specifically, a trial and failure of Inflectra and Renflexis products first.	Update	2/15/2021
Bynfezia (in Octreotide)	octreotide	New octreotide formulation, indicated to reduce blood levels of growth hormone (GH) and insulin-like growth factor 1 (IGF-1) [somatomedin C] in adult patients with acromegaly who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses. Treatment of adult patients with severe diarrhea and flushing episodes associated with metastatic carcinoid tumors; and treatment of adult patients with the profuse watery diarrhea	Update	2/15/2021

		associated with vasoactive intestinal peptide (VIP)-secreting tumors. Bynfezia will be added to the Sandostatin guideline with criteria to mirror the existing octreotide products with the addition of a requirement for trial and failure of generic octreotide. The guideline will be renamed to "Octreotide Products.".		
Fensolvi (in Gonadotropin-Releasing Hormone Agonists)	leuprolide acetate	Indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP). Fensolvi will be added to the Gonadotropin-Releasing Hormone Agonist guideline with criteria that mirrors the other leuprolide formulations for a diagnosis of CPP.	Update	2/15/2021
Alunbrig	brigatinib	Expanded indication for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test. Previously approved after treatment with crizotinib and is now approved first-line. Criteria will be modified to remove the requirement of a trial and failure or intolerance to Xalkori (crizotinib).	Update	2/15/2021
Inlyta	axitinib	New indication to be used in combination with avelumab (Bavencio) or pembrolizumab (Keytruda) for the first-line treatment of patients with advanced renal cell carcinoma (RCC). Previously approved for second-line advanced RCC. Criteria will be updated for this new indication. The following changes will be made to the guideline: 1) Diagnosis of renal cell carcinoma;	Update	2/15/2021

		2) One of the following: a) Disease has relapsed, or b) Diagnosis of stage IV disease AND 3) One of the following: a) Used as first-line treatment in combination with one of the following: avelumab (Bavencio) or pembrolizumab (Keytruda), or b) Used after failure of one prior systemic therapy; and 4) Prescribed by an oncologist.		
Pomalyst	pomalidomide	New indication for the treatment of adult patients with acquired immunodeficiency syndrome (AIDS)-related Kaposi sarcoma after failure of highly active antiretroviral therapy (HAART) and Kaposi sarcoma in adult patients who are human immunodeficiency virus (HIV)-negative. The criteria will be updated for this new indication. Initial authorization criteria requires: 1) One of the following: a) Both of the following: Diagnosis of AIDS-related Kaposi sarcoma and patient has failed highly active antiretroviral therapy (HAART), OR b) Both of the following: Diagnosis of Kaposi sarcoma and patient is HIV-negative; and 2) Prescribed by a hematologist/oncologist.	Update	2/15/2021
Lynparza	olaparib	Two new indications for Lynparza: 1) In combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either: a deleterious or suspected deleterious BRCA mutation, and/or genomic instability; and 2) Treatment of adult patients with deleterious or suspected	Update	2/15/2021

		deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. The criteria will be updated with for this new indication. Initial criteria requires: <u>Epithelial ovarian, Fallopian tube, Primary peritoneal cancer:</u> 1) Diagnosis of one of the following: advanced epithelial ovarian cancer, advanced fallopian tube cancer, or advanced primary peritoneal cancer; 2) Cancer is associated with homologous recombination deficiency (HRD)-positive status (defined by either: a deleterious or suspected deleterious BRCA mutation, and/or genomic instability) as detected by an appropriate lab test; 3) Patient has had a complete or partial response to first-line platinum-based chemotherapy (such as carboplatin, cisplatin); 4) Used in combination with bevacizumab (brand names include, Avastin, Mvasi); 5) Lynparza will be used as first-line maintenance treatment; and 6) Prescribed by an oncologist. <u>Prostate cancer:</u> 1) Diagnosis of metastatic castration-resistant prostate cancer; 2) Presence of deleterious or suspected deleterious homologous recombination repair (HRR) gene mutation as detected by an appropriate lab test); 3) Disease has progressed following prior treatment with one of the following: enzalutamide (Xtandi) or abiraterone (e.g., Zytiga, Yonsa); and		

		4) Prescribed by or in consultation with an oncologist or urologist.		
Rubraca	rucaparib cansylate	New indication for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy. The criteria will be updated with criteria for this new indication. Initial authorization criteria requires: 1) Diagnosis of metastatic castration-resistant prostate cancer (mCRPC); 2) Presence of deleterious BRCA mutation as detected by an appropriate lab test 3) Patient has received previous treatment with both of the following: a) Androgen receptor-directed therapy [e.g., Erleada (apalutamide), Xtandi (enzalutamide), Zytiga (abiraterone)], and b) A taxane-based chemotherapy [e.g., docetaxel, Jevtana (cabazitaxel)]; and 4) Prescribed by an oncologist or urologist.	Update	2/15/2021
Zejula	Niraparib tosylate	New indication for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy. The criteria will be updated for this new indication. Initial criteria requires: 1) Diagnosis of one of the following: advanced epithelial ovarian cancer, advanced fallopian tube cancer, or advanced primary peritoneal cancer;	Update	2/15/2021

		2) Used for maintenance treatment in patients who are in a complete or partial response to first-line platinum-based chemotherapy (such as, cisplatin, carboplatin); and 3) Prescribed by an oncologist		
Prolia	denosumab	Update to require a trial of a bisphosphonate for the non-metastatic prostate cancer indication.	Update	2/15/2021
Compounded Drugs	Multiple	Updated the general compound criteria to require two medical journal articles that support the need for medication.	Update	2/15/2021
Krystexxa	pegloticase	Criteria will now require one of the following: 1) History of at least two gout flares in the previous 12 months OR 2) At least 1 gouty tophus AND 3) Prescribed by a rheumatologist or nephrologist.	Update	2/15/2021
Dupixent	dupilumab	For moderate to severe atopic dermatitis, criteria will no longer require a trial of Eucrisa. Additionally, a trial and failure of a strong topical corticosteroid OR a topical drug such as tacrolimus or pimecrolimus will be required, instead of a trial of both. The drug is now approved for patients 6 years of age and older.	Update	1/15/2021