Summary of Utilization Management (UM) Program Changes

January 2019

Brand Name	Generic Name	Utilization Update Summary	Type	Effective Date
Nourianz	istradefylline	New product indicated as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease experiencing "OFF" episodes. A new PA guideline has been created for Nourianz. Criteria requires: 1) Diagnosis of Parkinson's Disease; 2) Patient is experiencing "off" episodes; 3) Used in combination with carbidopa/levodopa at a maximally tolerated dose (maximally tolerated dose applies to Commercial only); 4) Trial and failure, contraindication or intolerance to two of the following: a) MAO-B Inhibitors (e.g., rasagiline, selegiline), b) Dopamine Agonist (e.g., pramipexole, ropinirole), c) COMT Inhibitor (e.g., entacapone); and 5) Prescribed by or in consultation with a neurologist. Reauthorization criteria requires: 1) Documentation of positive clinical response to therapy, and 2) Used in combination with carbidopa/levodopa at a maximally tolerated dose. Initial and reauthorization duration is for 12 months.	New	04/27/2020
Trikafta	elexacaftor, tezacaftor, and ivacaftor	Indicated for the treatment of cystic fibrosis (CF) in patients aged 12 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. If the patient's genotype is	New	04/27/2020

		unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation. A new PA guideline was created for Trikafta. Criteria requires: 1) Patient is 12 years of age or older, 2) Diagnosis of CF, 3) Patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by a FDA-cleared cystic fibrosis mutation test or a test performed at a Clinical Laboratory Improvement Amendments (CLIA)-approved facility, and 4) Prescribed by or in consultation with a pulmonologist or a specialist affiliated with a CF care center. Reauthorization confirms documentation of positive clinical response to Trikafta (elexacaftor/tezacaftor/ivacaftor) therapy (e.g., improvement in lung function or decreased number of pulmonary exacerbations). Initial and reauthorization duration is 12 months.		
Erleada	apalutamide	Indicated for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC). PA guidelines will be updated with criteria for this new indication. Initial criteria requires: 1) Diagnosis of metastatic, castration-sensitive prostate cancer (mCSPC), 2) One of the following: used in combination with gonadotropin-release hormone (GnRH) analog [e.g., Lupron (leuprolide), Trelstar (triptorelin), etc.] or patient received bilateral orchiectomy,	Update	04/27/2020

		and 3) Prescribed by or in consultation with an oncologist or urologist. Reauthorization criteria requires that the patient does not show evidence of disease progression while on Erleada (apalutamide) therapy. Authorization duration is 12 months.		
Lenvima	lenvatinib	Indicated to be used in combination with Keytruda (pembrolizumab), for the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation. PA guidelines will be updated with criteria for this new indication. Initial criteria requires: 1) Diagnosis of advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), 2) Patient has disease progression following systemic therapy, 3) Used in combination with Keytruda (pembrolizumab) therapy, 4) Patient is not a candidate for curative surgery or radiation, and 5) Prescribed by or in consultation with an oncologist. Authorization duration is 12 months.	Update	04/27/2020
Nucala	mepolizumab	Expanded indication for patients 6 years and older as add-on maintenance treatment of patients with severe asthma with an eosinophilic phenotype. Previous lower age was 12 years old. Dosed as 40 mcg per 28 weeks; existing 100 mcg vials or	Update	04/27/2020

		syringe formulations are to be used. PA guidelines will be updated to allow use in patients 6 years of age and older.		
Ofev	nintedanib	Indicated to slow the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD). The Idiopathic Pulmonary Fibrosis Agents guidelines will be renamed to *Interstitial Lung Disease Agents* guidelines, and will be updated with criteria for this new indication for Ofev. Initial criteria requires: 1) Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by the following: a) Exclusion of other known causes of interstitial lung disease (ILD) (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity) AND b) One of the following: i) In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (e.g., 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; 2) Not being used in combination with Esbriet, and 3) Prescribed by or in consultation with a pulmonologist. Reauthorization criteria requires documentation	Update	04/27/2020

		of positive clinical response to therapy. Approval duration is 12 months..		
Harvoni	ledipasivir / sofosbuvir	Expanded indication for the treatment of adults and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV): 1) genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis; 2) genotype 1 infection with decompensated cirrhosis, for use in combination with ribavirin; 3) genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, for use in combination with ribavirin. In addition to the currently available 90/400 mg tablet, new 33.75mg/150 mg and 45/200 mg pellet formulations and 45/200 mg tablet have been approved to support the new expanded pediatric indications. Harvoni PA guidelines will be updated due to these expanded indications. QLs will apply: 1 tablet/packet per day for all, except 2 per day for the 45/200 mg strengths.	Update	04/27/2020
Sovaldi	sofosbuvir	Expanded indication for the treatment of chronic HCV genotype 2 or 3 infection in adults and pediatric patients 3 years of age and older without cirrhosis or with compensated cirrhosis for use in combination with ribavirin. Previously approved for this indication in pediatric patients 12 years of age and older or weighing at least 35 kg. In addition to the currently available 400 mg tablet, new	Update	04/27/2020

		150mg and 200mg pellet formulations and 200 mg tablet formulations have been approved to support new expanded pediatric indication. Sovaldi PA guidelines will be updated due to these expanded indications. Additionally, criteria sections for use in combination with Daklinza will be removed since Daklinza has been discontinued. QLs will apply: Commercial: 1 tablet/packet per day for all, except 2 per day for the 200 mg strengths.		
Mavyret	glecaprevir /pibrentasvir	Treatment course for treatment naïve patients shortened to 8 weeks: Treatment of adult and pediatric patients 12 years and older or weight at least 45 kg with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis. PA guideline will have the criteria coverage duration updated to 8 weeks for the treatment naïve population. Maintain QL of 3 tablets per day.	Update	04/27/2020
Entyvio	onabotulinumtoxinA	Update for Entyvio for Ulcerative Colitis to now require a trial of 1 conventional agent AND 2 first line agents out of Humira, infliximab, Simponi, and Stelara. Previously only required 1 conventional agent and 1 TNF inhibitor.	Update	04/27/2020
Cutaquig (as part of Immune Globulins)	Immune globulins	Update for Cutaquig to require a trial of both of the following: Hizentra and Cuvitru, OR allow continuation of current Cutaquig therapy.	Update	04/27/2020

Xolair	omalizumab	Added examples of inhaled corticosteroids for asthma in the reauthorization criteria. For chronic idiopathic urticaria, added examples of H1 antihistamines (e.g., cetirizine, fexofenadine), H2 antagonists (e.g., famotidine, cimetidine), and leukotriene receptor antagonists (e.g., montelukast).	Update	04/27/2020
Repatha and Praluent (PCSK9 Inhibitors)	alirocumab and evolocumab	There will be an addition of a requirement for submission of medical records (e.g., chart notes) for the statin and ezetimibe requirements for both initial and reauthorization with an added note that [prescription history may be used in conjunction as documentation of medication use, dose, and duration].	Update	04/27/2020
Sporanox (as part of Azole Antifungals)	itraconazole	Updating criteria to remove the statement that the "medication will not be used in combination with another CGRP inhibitor" in order to streamline reviews since a duplicate therapy check can be done using point-of-sale messaging.	Update	04/27/2020
Aimovig, Ajovy, and Emgality (CGRP Inhibitors)	erenumab, fremanezumb, and galcanezumab	Updating criteria to remove the statement that the "medication will not be used in combination with another CGRP inhibitor" in order to streamline reviews since a duplicate therapy check can be done using point-of-sale messaging.	Update	04/27/2020
Erbitux	cetuximab	Added examples for platinum-based chemotherapy and intensive chemotherapy, also updated language regarding chemotherapies containing irinotecan/oxaliplatin for clarity.	Update	04/27/2020
Selzentry	maraviroc	Removed reauthorization criteria and allow for continuation of prior Selzentry therapy.	Update	04/27/2020
CNS Quantity Limit Override	various	1. Quantity limit criteria for quantities below the FDA max	Update	04/27/2020

		dose for an indication of ADHD will be modified to allow for approval for strength/doses that are commercially unavailable or if patient is on a dose alternating schedule. Current criteria is approval for dose titration purposes only. 2 . Quantity limit criteria for quantities that exceed the FDA max dose for off-label uses will be removed from this guideline. All QL override		
Rituxan / Truxima		For Rituxan, the expanded indication to be used in combination with glucocorticoids, for the treatment of Granulomatosis with Polyangiitis and Microscopic Polyangiitis for children 2 years of age and older, did not require any criteria change. First time biosimilar of Rituxan has now launched. Truxima is approved for the treatment of adult patients with: 1) Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell Non-Hodgkin's Lymphoma (NHL) as a single agent; 2) Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy; 3) Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy; 4) Previously	Update	04/27/2020

		untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens; and 5) Previously untreated and previously treated CD20-positive Chronic Lymphocytic Leukemia (CLL), in combination with fludarabine and cyclophosphamide (FC).		
Stelara	ustekinumab	Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC). The Stelara PA guideline will be updated with criteria for this new indication. The criteria for UC align with the criteria for Crohn's Disease. Reauthorization criteria for the approved indications require documentation of a positive clinical response to Stelara therapy.	Update	04/27/2020
Aklief (as part Topical Retinoid Products)	trifarotene	New topical retinoid indicated for the topical treatment of acne vulgaris in patients 9 years of age and older. Added to the existing Topical Retinoid Agents PA with age bypass for those 25 years and younger. Criteria will mirror other non-preferred topical retinoid agents (requiring a trial of three formulary products).	Update	04/27/2020
Testosterone	various	Update for branded injectable products to require a trial of generic testosterone cypionate and generic testosterone enanthate. Additionally, branded transdermal products and nasal testosterone require a trial of generic testosterone gel. Methyltestosterone requires a	Update	04/27/2020

		trial of Androderm (testosterone patch) and generic testosterone gel.		
Orfadin	nitisinone	New generic for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine This generic will be added to the Orfadin guideline with criteria similar to brand Orfadin, except the generic will not include a requirement to try brand Nityr (nitisinone).	Update	04/27/2020
Provigil, Nuvigil	Modafinil and armodafinil	1. Rename Obstructive sleep apnea/hypopnea syndrome (OSAHS) indication to Obstructive sleep apnea (OSA) to align with package insert and rename Shift work sleep disorder indication to Shift work disorder to align with package insert. 2. Remove criterion stating sleep disturbance causes clinically significant distress or significant impairment in occupational functioning from SWD criteria. 3. Added an embedded step through modafinil for any criteria which targeted Brand Provigil.	Update	04/27/2020
Non-formulary Drug Exceptions Process	various	Updated criteria to indicate that if only OTC alternatives are available that the patient has tried or has contraindications or intolerance to 3 OTC equivalents, unless there are only 1 or 2 OTC equivalents then the patient has tried all.		04/27/2020