

To: IEHP Provider Network
From: IEHP Pharmaceutical Services
Date: June 9, 2023
Subject: **May 2023 Pharmacy & Therapeutics Update**

May 2023 Pharmacy & Therapeutics Subcommittee Update

The following tables detail changes that were approved by the Pharmacy and Therapeutics (P&T) Subcommittee in May 2023.

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For any questions, suggestions, or if you would like a printed copy of the IEHP Formulary Book or Clinical Practice Guideline, please call us at (909) 890-2049. As a reminder, the updated formulary information and Clinical Practice Guidelines are available at www.iehp.org.

Sincerely,
IEHP Pharmaceutical Services

NOTE: IEHP is a generic mandated health plan. Brand name drugs are not covered unless indicated or if generic is not available. The FDA recommended maximum dosage limit is applied.

IEHP Medicare Pharmacy Benefit Formulary Updates

We would like to inform you of the following changes to the **2023 IEHP Medicare Formulary** that were approved by the Pharmacy and Therapeutics Subcommittee in May 2023.

As a reminder, all **Medi-Cal** formulary decisions are no longer made by IEHP and should be addressed with **Medi-Cal Rx** directly.

*Legend for **Status Change** column

AF = Add to Formulary	AR = Age Restriction
BOLD = Brand Name	C1 = Code 1 drugs are restricted to certain medical conditions or specific circumstances
DS = Days' Supply	PA = Prior Authorization
QL = Quantity Limit	RF = Remove from Formulary
ST = Step Therapy	R-PA = Remove Prior Authorization
R-QL = Remove Quantity Limit	R-C1 = Remove Code 1 restriction
	RSOC = Remove Site of Care

IEHP <u>Medicare</u> Pharmacy Benefit Formulary Updates		
Drug Name	Strength & Dosage Form	Status Change*
albuterol sulfate	90 mcg/actuation HFA aerosol inhaler (NDA020983) and (NDA020503)	<ul style="list-style-type: none"> • AF • Effective 03/01/2023
amlodipine-valsartan-hydrochlorothiazide	5 mg-160 mg-12.5 mg 5 mg-160 mg-25 mg 10 mg-160 mg-12.5 mg 10 mg-160 mg-25 mg 10 mg-320 mg-25 mg	<ul style="list-style-type: none"> • AF • QL 1/1 ds • Effective 05/01/2023
Auvelity ER (dextromethorphan-bupropion)	45-105 mg tablet	<ul style="list-style-type: none"> • AF • PA (New Starts) • QL 2/1 ds • Effective 03/01/2023
azithromycin	250 mg tablet (6 pack) 500 mg tablet (3 pack)	<ul style="list-style-type: none"> • AF • Effective 03/01/2023
epinephrine	0.3 mg auto-injection (0.3 ml)	<ul style="list-style-type: none"> • AF • Effective 04/01/2023
Gleostine (lomustine)	10 mg capsule 40 mg capsule 100 mg capsule	<ul style="list-style-type: none"> • AF • PA (New Starts) • Effective 03/01/2023
haloperidol decanoate	100 mg/ml vial 250 mg/5 ml vial (50 mg/ml (1ml))	<ul style="list-style-type: none"> • AF • Effective • 04/01/2023
Heplisav-B (hepatitis B vaccine, recombinant, adjuvanted)	20 mcg/0.5 ml syringe	<ul style="list-style-type: none"> • AF • PA (BvD) • Effective 04/01/2023
Jaypirca (pirtobrutinib)	50 mg tablet 100 mg tablet	<ul style="list-style-type: none"> • AF • PA (New Starts) • QL 6/1 ds (50 mg tablet) • QL 3/1 ds (100 mg tablet) • Effective 05/01/2023

Drug Name	Strength & Dosage Form	Status Change*
Krazati (adagrasib)	200 mg oral tablet	<ul style="list-style-type: none"> • AF • PA (New Starts) • QL 6/1 DS • Effective 04/01/2023
lamotrigine	25 mg disintegrating tablet 50 mg disintegrating tablet 100 mg disintegrating tablet 200 mg disintegrating tablet 25 mg (35) tablets in a dose pack 25 mg (42)-100 mg (7) tablets in a dose pack 25 mg (84)-100 mg (14) tablets in a dose pack 25 mg (14)-50 mg (14)-100 mg (7) tablet, disintegrating, pack 25 mg (21)-50 mg (7) tablet, disintegrating, pack 50 mg (42)-100 mg (14) tablet, disintegrating, pack	<ul style="list-style-type: none"> • AF • Effective 05/01/2023
leuprolide depot	22.5 mg intramuscular vial	<ul style="list-style-type: none"> • AF • PA (New Starts) • Effective 04/01/2023
lurasidone	20 mg tablet 40 mg tablet 60 mg tablet 80 mg tablet 120 mg tablet	<ul style="list-style-type: none"> • AF • PA (New Starts) • QL 1/1 ds • QL 2/1 ds (80 mg tablet only) • Effective 05/01/2023
Lytgobi (futibatinib)	12 mg dose (3x 4mg tablet) 16 mg dose (4x 4mg tablet) 20 mg dose (5x 4 mg tablet)	<ul style="list-style-type: none"> • AF • PA (New Starts) • Effective 05/01/2023
Orserdu (elacestrant)	86 mg tablet 345 mg tablet	<ul style="list-style-type: none"> • AF • PA (New Starts) • QL 3/1 ds (86 mg) • QL 1/1 ds (345 mg) • Effective 05/01/2023
Oxbryta (voxelotor)	300 mg tablet	<ul style="list-style-type: none"> • AF • PA • QL 9/1 DS • Effective 3/1/2023
Ozempic (semaglutide)	0.25 mg or 0.5 mg (2mg/1.5 ml) subcutaneous pen injector 0.25 mg or 0.5 mg (2 mg/3 ml) subcutaneous pen injector 1 mg/dose (4 mg/3ml subcutaneous pen injector) 2 mg/ dose (8 mg/3 ml)	<ul style="list-style-type: none"> • AF • Effective 05/01/2023
pirfenidone	267 mg capsule	<ul style="list-style-type: none"> • AF • PA • QL = 9/1 ds • Effective 04/01/2023
quetiapine	150 mg tablet	<ul style="list-style-type: none"> • AF • QL = 2/1 ds • Effective 05/01/2023

Drug Name	Strength & Dosage Form	• Status Change*
Rezlidhia (olutasidenib)	150 mg oral capsule	<ul style="list-style-type: none"> • AF • PA (New Starts) • QL=2/1 ds • Effective 01/01/2023
roflumilast	250 mcg tablet	<ul style="list-style-type: none"> • AF • PA • Effective 03/01/2023
Skyrizi (Risankizumab-rzaa)	on-body 180 mg/1.2 ml wear injection	<ul style="list-style-type: none"> • AF • PA • Effective 03/01/2023
sodium oxybate	0.5 g/ml solution	<ul style="list-style-type: none"> • AF • PA • Effective 04/01/2023
subvenite	starter (blue) kit 25 mg kit (35) tablets in a dose pack starter (green) kit 25 mg (840- 100 mg (14) tablet, dose pack starter (orange) kit 25 mg (42)-100 mg (7) tablet, dose pack	<ul style="list-style-type: none"> • Af • Effective 05/01/2023
subvenite	25 mg tablet 100 mg tablet 150 mg tablet 200 mg tablet	<ul style="list-style-type: none"> • AF • Effective 05/01/2023
Sunlenca (lenacapavir)	4-300 mg tablet 5-300 mg tablet	<ul style="list-style-type: none"> • AF • Effective 04/01/2023
Tadliq (tadalafil)	20 mg/5 ml oral suspension	<ul style="list-style-type: none"> • AF • PA • QL = 10/1 ds • Effective 04/01/2023
Takhzyro (Lanadelumab-flyo)	150 mg/ml subcutaneous syringe 300 mg/2 ml (150 mg/ml) subcutaneous syringe	<ul style="list-style-type: none"> • AF • PA • QL=0.15 /1 ds • Effective 05/01/2023
topiramate ER	25 mg capsule 25 mg sprinkle capsule 50 mg capsule 50 mg sprinkle capsule 100 mg capsule 100 mg sprinkle capsule 150 mg sprinkle capsule 200 mg sprinkle capsule	<ul style="list-style-type: none"> • AF • QL=16/1 ds (25 mg) • QL=8/1 ds (50 mg) • QL=4/1 ds (100 mg) • QL=2/1 ds (150 mg, 200 mg) • Effective 05/01/2023
Ztalmy (ganaxolone)	50 mg/ml oral suspension	<ul style="list-style-type: none"> • AF • Effective 05/01/2023

Medicare Indication, Formulation, and Molecular Entity Updates by Drug	
Drug Name	Updated Information
Adacel (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed)	NEW FORMULATION To include immunization during the third trimester of pregnancy to prevent pertussis in infants younger than 2 months of age.
Altuviio (antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl (formerly known as Efanesoctocog alfa)	NEW MOLECULAR ENTITY Indicated for use in adults and children with Hemophilia A (congenital Factor VIII deficiency) for: (1) Routine prophylaxis to reduce the frequency of bleeding episodes; (2) On-demand treatment and control of bleeding episodes; and (3) Perioperative management of bleeding.
Atorvaliq (atorvastatin calcium)	NEW DOSAGE FORM To reduce the risk of: Myocardial infarction (MI), stroke, revascularization procedures, and angina in adults with multiple risk factors for coronary heart disease (CHD) but without clinically evident CHD; MI and stroke in adults with type 2 diabetes mellitus with multiple risk factors for CHD but without clinically evident CHD; Non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure, and angina in adults with clinically evident CHD. Adjunct to diet for the treatment of adults with hypertriglyceridemia
Austedo XR (Deutetrabenazine)	NEW MOLECULAR ENTITY Indicated in adults for the treatment of: Chorea associated with Huntington's disease and Tardive dyskinesia
Cibinqo (abrocitinib tablet)	NEW PATIENT POPULATION 12 years of age and older for the treatment of refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable
Combogesic (acetaminophen-ibuprofen)	NEW COMBINATION Mild to moderate acute pain
daptomycin (Xellia)	NEW FORMULATION Indicated for the treatment of: Complicated skin and skin structure infections (cSSSI) in adult and pediatric patients (1 to 17 years of age); Staphylococcus aureus bloodstream infections (bacteremia), in adult patients including those with right-sided infective endocarditis; Staphylococcus aureus bloodstream infections (bacteremia) in pediatric patients (1 to 17 years of age).
Daybue (trofinetide)	NEW MOLECULAR ENTITY Treatment of Rett syndrome (genetic mutation affecting brain development) in adults and pediatric patients 2 years of age and older
Dengvaxia (Dengue tetravalent vaccine, live)	NEW DATA ON IMMUNE RESPONSE To include data on the immune response to Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Adacel) when administered concomitantly with DENGVAXIA
Evkeeza VI (evinacumab-dgnb)	NEW PATIENT POPULATION Indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 5 years and older, with homozygous familial hypercholesterolemia (HoFH).
Eylea (aflibercept)	NEW INDICATION Treatment of Retinopathy of Prematurity (ROP)

Medicare Indication, Formulation, and Molecular Entity Updates by Drug	
Drug Name	Updated Information
fentanyl citrate injection	NEW FORMULATION An opioid analgesic supplement in general anesthesia
Filspari (sparsentan)	NEW MOLECULAR ENTITY Indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g.
Hyrimoz HCF (adalimumab)	NEW DOSAGE FORM Indicated for rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis
Illuccix (gallium Ga 68 gozetotide)	NEW PATIENT POPULATION Indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer: With suspected metastasis who are candidates for initial definitive therapy. With suspected recurrence based on elevated serum prostate-specific antigen (PSA) level. For selection of patients with metastatic prostate cancer, for whom lutetium Lu. 177 vipivotide tetraxetan PSMA-directed therapy is indicated.
Jesduvroq (daprodustat)	NEW MOLECULAR ENTITY For the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months
Joenja (leniolisib phosphate)	NEW MOLECULAR ENTITY Treatment of activated phosphoinositide 3-kinase delta (PI3K δ) syndrome (APDS) in adult and pediatric patients 12 years of age and older.
Kevzara (sarilumab)	NEW INDICATION Treatment of adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper
Lamzede (velmanase alfa-tycv)	NEW MOLECULAR ENTITY Indicated for the treatment of non-central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients.
Livmarli (maralixibat)	NEW PATIENT POPULATION Treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) aged 3 months and older.
Lutrate Depot Kit (leuprolide acetate)	NEW INDICATION Treatment of advanced prostate cancer
Mekinist (trametinib)	NEW PATIENT POPULATION and NEW FORMULATION (oral solution) Treatment of pediatric patients 1 year of age and older with low-grade glioma with a BRAF V600E mutation who require systemic therapy.
M-M-R II (measles, mumps, and rubella virus vaccine live)	NEW DATA ON INTRAMUSCULAR WORK To include safety and immunogenicity data that support the intramuscular route as an additional route of administration for M-M-R II, and associated product labeling changes
naloxone hydrochloride nasal spray	NEW FORMULATION Indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression for adults and pediatric patients.
Narcan (naloxone hydrochloride nasal spray)	PRESCRIPTION TO OVER-THE-COUNTER SWITCH Indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression
Odaetra (house dust mite (Dermatophagoides farinae and Dermatophagoides pteronyssinus) allergen extract)	NEW INDICATION To include use in adolescents 12 through 17 years of age

Medicare Indication, Formulation, and Molecular Entity Updates by Drug	
Drug Name	Updated Information
Prevduo (glycopyrrolate, neostigmine methylsulfate)	NEW MOLECULAR ENTITY A fixed dose combination of a cholinesterase inhibitor and antimuscarinic agent, is indicated in patients aged two years and above for the reversal of the effects of non-depolarizing neuromuscular blocking agents (NMBAs) after surgery, while decreasing the peripheral muscarinic effects (e.g., bradycardia and excessive secretions) associated with cholinesterase inhibition following NMBA reversal administration
ProQuad (measles, mumps, rubella, and varicella virus vaccine live)	NEW DATA ON INTRAMUSCULAR ROUTE To include safety and immunogenicity data that support the intramuscular route as an additional route of administration for ProQuad, and associated product labeling changes.
Revatio tablet (sildenafil citrate)	NEW PATIENT POPULATION Indicated in pediatric patients 1 to 17 years old for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise ability and, in pediatric patients too young to perform standard exercise testing, pulmonary hemodynamics thought to underlie improvements in exercise.
Revatio oral suspension (sildenafil citrate)	NEW PATIENT POPULATION Indicated in pediatric patients 1 to 17 years old for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise ability and, in pediatric patients too young to perform standard exercise testing, pulmonary hemodynamics thought to underlie improvements in exercise.
Rezzayo (rezafungin)	NEW MOLECULAR ENTITY Treatment of candidemia and invasive candidiasis
Skyclarys (omaveloxolone)	NEW MOLECULAR ENTITY Treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.
Synjardy (empagliflozin and metformin)	NEW INDICATION Reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.
Synjardy XR (empagliflozin and metformin)	NEW INDICATION Reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.
Syfovre (pegcetacoplan)	NEW DOSAGE FORM Treatment of geographic atrophy secondary to age-related macular degeneration
Tafinlar (dabrafenib)	NEW PATIENT POPULATION Treatment of pediatric patients 1 year of age and older with low-grade glioma with a BRAF V600E mutation who require systemic therapy.
Tafinlar tablet for oral suspension (dabrafenib)	NEW FORMULATION Treatment of pediatric patients 1 year of age and older with low-grade glioma with a BRAF V600E mutation who require systemic therapy.
Takhzyro SC (Lanadelumab)	NEW PATIENT POPULATION Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 2 years and older.
Technetium TC-99M Mertiatide Kit	NEW FORMULATION Radioactive diagnostic agent indicated for use in the diagnosis of congenital and acquired renal abnormalities, renal failure, urinary tract obstruction, and calculi in adults and pediatric patients aged 30 days and older

Medicare Indication, Formulation, and Molecular Entity Updates by Drug	
Drug Name	Updated Information
Tezspire (tezepelumab-ekko)	NEW DOSAGE FORM Add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.
Trodelyv (sacituzumab govitecan-hziy)	NEW INDICATION Treatment of adult patients with unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting
Udenyca (pegfilgrastim)	NEW FORMULATION Cancer patients receiving myelosuppressive chemotherapy
vancomycin hydrochloride for injection	NEW FORMULATION Indicated in adult and pediatric patients less than 18 years of age as follows: Vancomycin Hydrochloride for Injection administered intravenously is indicated for the treatment of: Septicemia, Infective Endocarditis, Skin and Skin Structure Infections, Bone Infections, and Lower Respiratory Tract Infections. Vancomycin Hydrochloride for Injection administered orally is indicated for the treatment of: Clostridioides difficile-associated diarrhea, Enterocolitis caused by Staphylococcus aureus (including methicillin-resistant strains).
Varivax (varicella virus vaccine, live)	NEW DATA ON INTRAMUSCULAR ROUTE To include safety and immunogenicity data that support the intramuscular route as an additional route of administration for Varivax, and associated product labeling changes.
Verzenio (abemaciclib)	NEW INDICATION In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)- negative advanced or metastatic breast cancer. In combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node positive, early breast cancer at high risk of recurrence.
Vuity (pilocarpine hydrochloride ophthalmic solution)	NEW DOSING REGIMEN Treatment of presbyopia in adults
Zavzpret (nasal) (zavegepant)	NEW MOLECULAR ENTITY Acute treatment of migraine with or without aura in adults
Zynyz (retifanlimab-dlwr)	NEW MOLECULAR ENTITY Prophylaxis of invasive aspergillus and candida infections in patients aged 2 years up to 18 years.

Prior Authorization table available at: www.iehp.org > For Providers > Pharmacy Services > Clinical Information > Prior Authorization Drug Treatment Criteria

IEHP Pharmacy Policies, Prior Authorization Criteria, and Drug Class Criteria	
Document	Subcommittee Action
Pharmacy Prior Authorization Criteria	
Cimzia	<ul style="list-style-type: none"> • Added to Criteria: trial and failure of brand formulary alternatives to align with rebates. • Removed from Criteria: trial and failure of generic products.
Growth Hormone	<ul style="list-style-type: none"> • Updated Criteria • Created table for FDA indications covered for Growth Hormone • Added Drug Requiring Prior Authorization Review: Omnitrope and Zomacton • Removed Drug Require Prior Authorization Review: Zorbtive • Removed Authorization Criteria Requirement: failure or clinically significant adverse effects to the formulary alternative: Omnitrope. • Updated BMI criteria for Serostim • Updated References
Nucala	<ul style="list-style-type: none"> • Updated Criteria • Indication: Eosinophilic granulomatosis with polyangiitis (EGPA) • Updated Reauthorization Criteria: Documentation of one of the following: reduction in frequency and/or severity of relapses, reduction in severity and/or frequencies typical of EGPA, and reduction or discontinuation of doses of corticosteroid or immunosuppressive therapy absence of active vasculitis. • Removed Reauthorization Requirement: Recent claim within 180 days. • Updated Reauthorization Duration: from six months to 12 months • Updated References
Xolair	<ul style="list-style-type: none"> • Renewed with no changes. • Updated references
Zynteglo	<ul style="list-style-type: none"> • PA Criteria Added to Formulary • Exclusion Criteria: <ul style="list-style-type: none"> • Received prior allogenic HSCT or prior gene therapy. • Advanced liver disease • Positive for the presence of HIV type 1 or 2 • Prior malignancy or has current malignancy (with exception of adequately treated biopsied in situ carcinoma of the cervix uteri and basal or squamous cell carcinoma of the skin) • Severely elevated iron in the heart • White blood cell count less than $5 \times 10^9/L$ and/or platelet count less than $100 \times 10^9/L$, not related to hypersplenism. • Approval Duration: One time infusion per lifetime • Age Restrictions: 4 years to 50 years • Prescriber Restrictions: Hematologist or Transplant Specialist