Pulmonary Arterial Hypertension (PAH) Agents, Other – Oral

Therapeutic Class Review

New York Medicaid
Drug Utilization Review Board Meeting
September 21, 2023

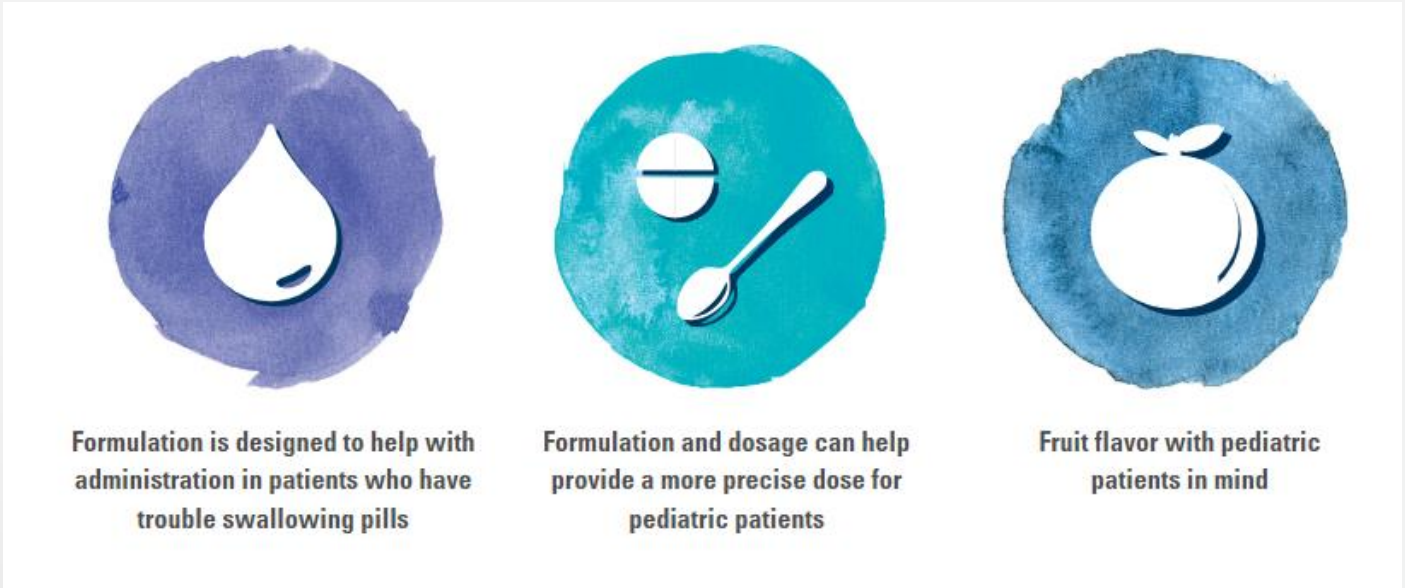
New Clinical Information

- New Strength: Tracleer® (bosentan)
- Label Revision: Opsumit® (macitentan)

Tracleer® (bosentan)

➢ New Strength:

- Food & Drug Administration (FDA) approved a 32 mg round tablet for oral suspension for pediatric patients (aged 3 years and older) that is bisected on one side; already approved is a 32 mg clover-shaped tablet for oral suspension that is quadrisected.
- 32 mg pediatric formulation is dispersible in water and has a fruit flavor



https://www.tracleer.com/hcp/managing-ped-patients

Opsumit® (macitentan)

➢ Label Revisions:

- Package Insert updated to include flushing to the ADR section.
- REMS updated regarding outpatient pharmacy certification and REMS Dispensing Authorization (RDA) processes to ensure REMS requirements are met prior to dispensing. Updated the Prescriber and Pharmacy Guide to include additional instructions for pharmacies to provide reasons for dispensing greater than 30 days for a female of reproductive potential and to provide reasons for treatment interruption. Updated the REMS assessment timetable.

Opsumit [package insert]. Titusville, NJ; Actelion Pharmaceuticals; June 2023

Pulmonary Arterial Hypertension (PAH) Agents, Other – Oral

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
III. Cardiovascular		
Pulmonary Arterial Hypertension (PAH) Agents, Other – Oral		
ambrisentan (gen Letairis) bosentan tablets (gen Tracleer®)	Adempas® Letairis® Opsumit® Orenitram® ER tablet, dosepack Tracleer® tablet for suspension, tablet Uptravi®	

Antimigraine Agents, Other Therapeutic Class Review

New York Medicaid
Drug Utilization Review Board Meeting
September 21, 2023

New Clinical Information

- New Drug Entity: Zavzpret™(zavegepant)
- New Indication: Qulipta™ (atogepant)
- Label Revisions: Ubrelvy™(ubrogepant), Qulipta™ (atogepant)

Zavzpret™ (zavegepant)

Indications and Usage:

- Calcitonin gene-related peptide receptor antagonist indicated for the acute treatment of migraine with or without aura in adults
- Not indicated for the preventive treatment of migraine

Dosage and Administration:

- The recommended dose is 10 mg given as a single spray in one nostril, as needed
- The maximum dose in a 24-hour period is 10 mg (one spray)
- The safety of treating more than 8 migraines in a 30-day period has not been established

Dosage Forms and Strengths:

- Nasal spray: 10 mg of zavegepant per device. Each unit-dose nasal spray device delivers a single spray containing 10 mg of zavegepant

Contraindications:

- Patients with a history of hypersensitivity reaction to zavegepant or to any of the components

Zavzpret [package insert]. New York, NY; Pfizer Labs; March 2023

Zavzpret™ (zavegepant)

➢ Warnings and Precautions:

- Hypersensitivity Reactions: If a serious hypersensitivity reaction occurs, discontinue and initiate appropriate therapy. Hypersensitivity Reactions including facial swelling and urticaria have occurred.

➢ Adverse Reactions:

- Most common adverse reactions (at least 2% of patients treated with ZAVZPRET and greater than placebo) were taste disorders, nausea, nasal discomfort, and vomiting.

➢ Drug Interactions:

- Avoid use with drugs that inhibit OATP1B3 or NTCP transporters.
- Avoid use with drugs that induce OATP1B3 or NTCP transporters.
- Avoid use of intranasal decongestants; if unavoidable, administer intranasal decongestants at least 1 hour after ZAVZPRET administration.

OATP = Organic anion transporting polypeptide
NTCP = Na+/taurocholate cotransporting polypeptide

Zavzpret [package insert]. New York, NY; Pfizer Labs; March 2023

Zavzpret™ (zavegepant)

Specific Populations:

- Avoid use in patients with severe hepatic impairment
- Avoid use in patients with CLcr < 30 mL/min

Clinical Comparative Studies (within class):

- None

Storage and Handling:

- Store at controlled room temperature, 20°C to 25°C (68°F to 77°F); with excursions permitted between 15°C to 30°C (59°F to 86°F)
- Do not freeze. Do not test spray, prime, or press the plunger before use.

Zavzpret [package insert]. New York, NY; Pfizer Labs; March 2023

Qulipta™ (atogepant)

- **New Indication:**
  - FDA approved for the preventive treatment of chronic migraine in adults; previously approved only to prevent episodic migraine.
  - The recommended dose for chronic migraine is 60 mg once daily.
  - Severe Renal Impairment or End-Stage Renal Disease (ESRD):
    - Chronic migraine: Avoid use.

Qulipta [package insert]. North Chicago, IL; AbbVie; June 2023

Antimigraine Agents, Other

➢ Label Revisions:

- **Qulipta (atogepant)** - updated with recommendations to avoid use in patients with chronic migraine also taking a strong CYP3A4 inhibitor, or strong/moderate/weak CYP3A4 inducer, or severe renal impairment/ESRD; also recommended dose of 30 mg in patients taking OATP inhibitors. Contraindications and Warnings of hypersensitivity reactions to atogepant were added. ADR section updated with data from chronic migraine studies. Post-marketing experience data added.

- **Ubrelvy (ubrogepant)** - updated to include serious hypersensitivity to ubrogepant or any of its components in Contraindications section; reactions have included anaphylaxis, dyspnea, & facial or throat edema. Hypersensitivity has also been added to Warnings and Precautions & Post-marketing Experience subsections. New information added to pharmacokinetics subsection to state that no significant pharmacokinetic interactions were found between ubrogepant and erenumab, galcanezumab, & atogepant.

Qulipta [package insert]. North Chicago, IL; AbbVie; June 2023
Ubrelvy [package insert]. North Chicago, IL; AbbVie; June 2023

Antimigraine Agents, Other

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
IV. Central Nervous System		
Antimigraine Agents, Other ST, F/Q/D		
Ajovy® Emgality® Nurtec™ ODT	Aimovig® Emgality® 100mg syringe Qulipta™ Reyvow™ Ubrelvy™ Zavzpret™	**STEP THERAPY (ST)** **Acute treatment of migraine** • Trial of a product from the Antimigraine Agents-Triptan class **Prevention of migraine** • Trial of 2 FDA approved or compendia supported migraine prevention products from other drug classes

Agent	F/Q/D
Aimovig	1 syringe/30 days
Emgality 120 mg	2 syringes/30 days
Emgality 100 mg	3 syringes/30 days
Ajovy	3 syringes/90 days
Reyvow	8 units/30 days
Ubrelvy	16 units/30 days
Nurtec™ ODT	24 units/40 days
Qulipta	30 units/30 days
Zavzpret®	8 units/30 days

Antipsychotics – Injectable Therapeutic Class Review

New York Medicaid
Drug Utilization Review Board Meeting
September 21, 2023

New Clinical Information

- New Drug Formulations: Uzedy™(risperidone),
  Abilify Asimtufii® (aripiprazole)

Uzedy™ (risperidone)

➢ Indications and Usage:

- Atypical antipsychotic indicated for the treatment of schizophrenia in adults

➢ Dosage and Administration:

- Establish tolerability with oral risperidone prior to initiating Uzedy
- Administer by subcutaneous injection in the abdomen or upper arm by a healthcare professional. Do not administer by any other route
- Initiate Uzedy at the clinically appropriate dose using the following table:

Prior Oral Risperidone Therapy	UZEDY Dosage Once Monthly	UZEDY Dosage Once Every 2 Months
2 mg of oral risperidone per day	50 mg	100 mg
3 mg of oral risperidone per day	75 mg	150 mg
4 mg of oral risperidone per day	100 mg	200 mg
5 mg of oral risperidone per day	125 mg	250 mg

Uzedy [package insert]. Parsippany, NJ; Teva; May 2023

Uzedy™ (risperidone)

Dosage Forms and Strengths:

- Extended-release injectable suspension: 50 mg/0.14 mL, 75 mg/0.21 mL, 100 mg/0.28 mL,125 mg/0.35 mL, 150 mg/0.42 mL, 200 mg/0.56 mL, and 250 mg/0.7 mL single-dose prefilled syringes

Contraindications:

- Known hypersensitivity to risperidone, paliperidone, or to any of the components in Uzedy

Warnings and Precautions:

- Cerebrovascular Adverse Reactions, in Elderly Patients with Dementia-Related Psychosis: Increased incidence of cerebrovascular reactions (e.g., stroke, transient ischemia attack).
- Neuroleptic Malignant Syndrome (NMS): Manage with immediate discontinuation and close monitoring.
- Tardive Dyskinesia: Discontinue treatment if clinically appropriate.
- Metabolic Changes: Monitor for hyperglycemia/diabetes mellitus, dyslipidemia, and weight gain.
- Hyperprolactinemia: Prolactin elevations occur and persist during chronic administration. Longstanding hyperprolactinemia, when associated with hypogonadism, can lead to decreased bone density in females and males.
- Orthostatic Hypotension and Syncope: Monitor heart rate and blood pressure and warn patients with known cardiovascular disease or cerebrovascular disease, and risk of dehydration or syncope.
- Leukopenia, Neutropenia, and Agranulocytosis: Perform complete blood counts (CBC) in patients with a history of clinically significant low white blood cell count (WBC) or history of leukopenia or neutropenia. Consider discontinuing if a clinically significant decline in WBC occurs in the absence of other causative factors.
- Potential for Cognitive and Motor Impairment: Use caution when operating machinery.
- Seizures: Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold.
- Priapism: Priapism has been reported. Severe priapism may require surgical intervention.

Uzedy [package insert]. Parsippany, NJ; Teva; May 2023

Uzedy™ (risperidone)

Black Box Warning:

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death
- Uzedy is not approved for the treatment of patients with dementia-related psychosis

Adverse Reactions:

- The most common adverse reactions with risperidone (≥5% and greater than placebo) were parkinsonism, akathisia, dystonia, tremor, sedation, dizziness, anxiety, blurred vision, nausea, vomiting, upper abdominal pain, stomach discomfort, dyspepsia, diarrhea, salivary hypersecretion, constipation, dry mouth, increased appetite, increased weight, fatigue, rash, nasal congestion, upper respiratory tract infection, nasopharyngitis, and pharyngolaryngeal pain
- The most common injection site reactions with Uzedy (≥5% and greater than placebo) were pruritus and nodule

Drug Interactions:

- Strong CYP2D6 inhibitors (e.g., fluoxetine, paroxetine): Increase risperidone plasma concentration
- Strong CYP3A4 inducers (e.g., carbamazepine): Decrease plasma concentrations of risperidone

Specific Populations:

- Pregnancy: May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure
- Renal Impairment: titrate with oral risperidone (up to at least 2 mg daily) before initiating treatment
- Hepatic Impairment: titrate with oral risperidone (up to at least 2 mg daily) before initiating treatment
- Patients with Parkinson's Disease or Dementia with Lewy bodies: can experience increase sensitivity

Clinical Comparative Studies (within class):

- None

Uzedy [package insert]. Parsippany, NJ; Teva; May 2023

Abilify Asimtufii® (aripiprazole)

Indications and Usage:

Atypical antipsychotic indicated:

- For the treatment of schizophrenia in adults
- As maintenance monotherapy treatment of bipolar I disorder in adults

Dosage and Administration:

- For patients naïve to aripiprazole, establish tolerability with oral aripiprazole prior to initiating treatment with ABILIFY ASIMTUFII
- Administer by intramuscular injection in the gluteal muscle by a healthcare professional. Do not administer by any other route
- Recommended dosage is 960 mg administered once every 2 months as a single injection. Dose can be reduced to 720 mg in patients with adverse reactions
- Missed doses: Dosage adjustment may be required
- Known CYP2D6 poor metabolizers: Recommended dosage is 720 mg administered once every 2 months as a single injection

Abilify Asimtufii [package insert]. Rockville, MD; Otsuka; April 2023

Abilify Asimtufii® (aripiprazole)

Dosage Forms and Strengths:

- Extended-release injectable suspension: 960 mg/3.2 mL and 720 mg/2.4 mL single-dose pre-filled syringes

Contraindications:

- Known hypersensitivity to aripiprazole, or to any excipients of ABILIFY ASIMTUFII

Warnings and Precautions:

- Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis: Increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack, including fatalities)
- Neuroleptic Malignant Syndrome: Manage with immediate discontinuation and close monitoring
- Tardive Dyskinesia: Discontinue if clinically appropriate
- Metabolic Changes: Monitor for hyperglycemia/diabetes mellitus, dyslipidemia, and weight gain
- Pathological Gambling and Other Compulsive Behaviors: Consider dose reduction or discontinuation
- Orthostatic Hypotension and Syncope: Monitor heart rate and blood pressure and caution in patients with known cardiovascular or cerebrovascular disease, and risk of dehydration or syncope
- Leukopenia, Neutropenia, and Agranulocytosis: Perform complete blood counts (CBC) in patients with history of clinically significant low white blood cell count (WBC) or a history of leukopenia or neutropenia. Consider discontinuing if clinically significant decline in WBC in the absence of other causative factors
- Seizures: Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold
- Potential for Cognitive and Motor Impairment: Use caution when operating machinery

Abilify Asimtufii [package insert]. Rockville, MD; Otsuka; April 2023

Abilify Asimtufii® (aripiprazole)

➢ Black Box Warning:

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death
- ABILIFY ASIMTUFII is not approved for the treatment of patients with dementia-related psychosis

➢ Adverse Reactions

- Most commonly observed adverse reactions (incidence ≥5% and at least twice the rate of placebo) were increased weight, akathisia, injection site pain, and sedation

➢ Drug Interactions:

- Dosage adjustments for patients taking CYP2D6 inhibitors, CYP3A4 inhibitors, or CYP3A4 inducers for greater than 14 days

Factors	Dosage Recommendation
CYP2D6 Poor Metabolizers taking concomitant CYP3A4 inhibitors	Avoid use
Patients taking strong CYP2D6 **or** CYP3A4 inhibitors	720 mg
Patients taking CYP2D6 **and** CYP3A4 inhibitors	Avoid use
Patients taking CYP3A4 inducers	Avoid use

Abilify Asimtufii [package insert]. Rockville, MD; Otsuka; April 2023

Abilify Asimtufii® (aripiprazole)

➢ Specific Populations:

- Pregnancy: May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure
- Pediatric Use: safety and effectiveness have not been established
- Renal Impairment: no dosage adjustment required
- Hepatic Impairment: no dosage adjustment required

➢ Clinical Comparative Studies (within class):

- None

Abilify Asimtufii [package insert]. Rockville, MD; Otsuka; April 2023

Antipsychotics – Injectable

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
IV. Central Nervous System		
Antipsychotics – Injectable		
Abilify Maintena® Aristada® Aristada Initio® fluphenazine decanoate Haldol® decanoate haloperidol decanoate Invega Hafyera™ Invega Sustenna® Invega Trinza® Perseris™ Risperdal Consta® Zyprexa Relprevv®	Abilify Asimtufii® Uzedy™	

Growth Hormones Therapeutic Class Review

New York Medicaid
Drug Utilization Review Board Meeting
September 21, 2023

New Clinical Information

- New Drug Entity: Sogroya® (somapacitan-beco)

Sogroya® (somapacitan-beco)

➢ Indications and Usage:

SOGROYA® is a human growth hormone analog indicated for:

- Pediatric Patients: Treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous growth hormone (GH)
- Adults: Replacement of endogenous growth hormone in adults with growth hormone deficiency

➢ Dosage and Administration:

- SOGROYA® treatment should be supervised by a healthcare provider who is experienced in the diagnosis and management of patients with growth hormone deficiency
- SOGROYA® should be administered by subcutaneous injection once weekly, any time of the day, in the upper arms, thigh, abdomen or buttocks with regular rotation of injection site to avoid lipohypertrophy/lipoatrophy
- For pediatric patients with GHD:
  - Initiate with a dosage of 0.16 mg/kg body weight once weekly for treatment-naïve patients and patients switching from daily growth hormone (somatropin)
  - Individualize dosage for each patient based on the growth
  - Patients switching from daily human growth hormone to once-weekly SOGROYA® should choose the preferred day for the weekly dose and stop final dose of daily treatment the day before (or at least 8 hours before) taking the first dose of once-weekly somapacitan-beco
- For adult patients with GHD:
  - Initiate with a dosage of 1.5 mg once weekly for treatment naïve patients and patients switching from daily growth hormone
  - Increase the weekly dosage every 2 to 4 weeks by approximately 0.5 mg to 1.5 mg until the desired response has been achieved
  - Titrate the dosage based on clinical response and serum insulin-like growth factor-1 (IGF-1) concentrations
  - The maximum recommended dosage for adult GHD is 8 mg once weekly

Sogroya [package insert]. Plainsboro, NJ; Novo Nordisk Inc.; April 2023

Sogroya® (somapacitan-beco)

➢ Dosage Forms and Strengths:

- Liquid solution available in a ready-to-use prefilled pen
- Injection: 5 mg/1.5 mL (3.3 mg/mL) or 10 mg/1.5 mL (6.7 mg/mL) or 15 mg/1.5 mL (10 mg/mL) in a single patient-use prefilled pen

➢ Contraindications:

- Acute critical illness
- Active malignancy
- Hypersensitivity to somapacitan-beco or excipients
- Active proliferative or severe non-proliferative diabetic retinopathy
- Closed epiphyses in children used for longitudinal growth promotion
- Children with Prader-Willi syndrome who are severely obese or have severe respiratory impairment due to risk of sudden death

Sogroya [package insert]. Plainsboro, NJ; Novo Nordisk Inc.; April 2023

Sogroya® (somapacitan-beco)

Warnings and Precautions:

- Severe Hypersensitivity: Serious hypersensitivity reactions, including anaphylactic reactions and angioedema, may occur. In the event of an allergic reaction, seek prompt medical attention
- Increased Risk of Neoplasm: Monitor patients with preexisting tumors for progression or recurrence. Increased risk of a second neoplasm in childhood cancer survivors treated with somatropin – in particular meningiomas in patients treated with radiation to the head for their first neoplasm
- Glucose Intolerance and Diabetes Mellitus: may decrease insulin sensitivity, particularly at higher doses. Monitor glucose levels periodically in all patients receiving SOGROYA®, especially in patients with existing diabetes mellitus or at risk for its development
- Intracranial Hypertension (IH): Perform fundoscopic examinations prior to initiation and periodically thereafter. If papilledema is identified prior to initiation, evaluate the etiology and treat the underlying cause before initiating. If papilledema occurs with SOGROYA®, stop treatment
- Fluid Retention: May occur and may be dose dependent. Reduce dose as necessary
- Hypoadrenalism: Monitor patients for reduced serum cortisol levels and/or need for glucocorticoid dose increases in those with known hypoadrenalism
- Hypothyroidism: Monitor thyroid function periodically as hypothyroidism may occur or worsen after initiation
- Slipped Capital Femoral Epiphysis in Pediatric Patients: May develop. Evaluate children with the onset of a limp or persistent hip/knee pain
- Progression of Preexisting Scoliosis in Pediatric Patients: May develop
- Pancreatitis: Consider pancreatitis in patients with persistent severe abdominal pain
- Lipohypertrophy/lipoatrophy: May occur if SOGROYA® is administered in the same location over a long period of time. Rotate injection sites on a regular basis

Sogroya [package insert]. Plainsboro, NJ; Novo Nordisk Inc.; April 2023

Sogroya® (somapacitan-beco)

Adverse Reactions:

- Pediatric patients with GHD: Adverse reactions reported in ≥5% of patients are: nasopharyngitis, headache, pyrexia, pain in extremity, and injection site reaction
- Adult patients with GHD: Adverse reactions reported in >2% of patients are: back pain, arthralgia, dyspepsia, sleep disorder, dizziness, tonsillitis, peripheral edema, vomiting, adrenal insufficiency, hypertension, blood creatine phosphokinase increase, weight increase, anemia

Drug Interactions:

- Replacement Glucocorticoid Treatment: Patients treated with glucocorticoid for hypoadrenalism may require an increase in their maintenance or stress doses following initiation
- Cytochrome P450-Metabolized Drugs: SOGROYA® may alter the clearance. Monitor carefully if used with SOGROYA®
- Oral Estrogen: Larger doses of SOGROYA® may be required
- Insulin and/or Other Antihyperglycemic Agents: Dose adjustment of insulin or antihyperglycemic agent may be required

Specific Populations:

- Pregnancy: no available data
- Lactation: no information of presence in human milk
- Pediatric use: safety and efficacy established in pediatrics 2.5 years of age and older
- Geriatric Use: elderly patients may be more sensitive to drug and at increased risk for adverse reactions
- Hepatic Impairment: dose adjustment in moderate hepatic impairment, initiate 1 mg once weekly and use smaller increments when increasing the dose. The maximum dose should not exceed 4 mg once weekly.

Sogroya [package insert]. Plainsboro, NJ; Novo Nordisk Inc.; April 2023

Sogroya® (somapacitan-beco)

- **Clinical Comparative Studies (within class):**
  - Pediatric Patients with Growth Hormone Deficiency (GHD)
    - A randomized, open-label, active-controlled, parallel-group phase 3 study was conducted in 200 treatment-naïve, pediatric patients with growth hormone deficiency (GHD) (NCT03811535).
    - The primary efficacy endpoint was annualized height velocity at Week 52.
    - Treatment with once-weekly SOGROYA® for 52 weeks resulted in an annualized height velocity of 11.2 cm/year. Patients treated with daily somatropin achieved an annualized height velocity of 11.7 cm/year after 52 weeks of treatment.

Sogroya [package insert]. Plainsboro, NJ; Novo Nordisk Inc.; April 2023

Growth Hormones

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
VI. Endocrine and Metabolic Agents		
Growth Hormones CC, CDRP		
Genotropin® Norditropin®	Humatrope® Nutropin AQ® Omnitrope® Saizen® Skytrofa® Sogroya® Zomacton®	**CLINICAL DRUG REVIEW PROGRAM (CDRP)** • Prescribers or their authorized agents may call or submit a fax request for a PA for beneficiaries 18 years of age or older **CLINICAL CRITERIA (CC)** • Patient-specific considerations for drug selection include concerns related to use of a non-preferred agent for FDA-approved indications that are not listed for a preferred agent. • Confirm diagnosis of FDA-approved or compendia-supported indication

Sogroya [package insert]. Plainsboro, NJ; Novo Nordisk Inc.; April 2023

Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors Therapeutic Class Review

New York Medicaid
Drug Utilization Review Board Meeting
September 21, 2023

New Clinical Information

- New Drug Entity: Inpefa™(sotaglifozin)

Inpefa™ (sotagliflozin)

➢ Indications and Usage:

- INPEFA is a sodium-glucose cotransporter 2 (SGLT2) inhibitor indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with:
  1. heart failure or
  2. type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors

➢ Dosage and Administration:

- Correct volume status before starting INPEFA at 200 mg daily and titrate to 400 mg as tolerated. In patients with decompensated heart failure, begin dosing when patients are hemodynamically stable.
- Withhold INPEFA at least 3 days, if possible, prior to major surgery or procedures associated with prolonged fasting.

➢ Dosage Forms and Strengths:

- Tablets: 200 mg and 400 mg

➢ Contraindications:

- History of serious hypersensitivity reaction to Inpefa

Inpefa [package insert]. The Woodlands, TX; Lexicon Pharmaceuticals, Inc.; May 2023

Inpefa™(sotagliflozin)

➢ Warnings and Precautions:

- Diabetic Ketoacidosis in Patients with Type 1 Diabetes Mellitus and Other Ketoacidosis: Consider ketone monitoring in patients with type 1 diabetes mellitus and consider ketone monitoring in others at risk for ketoacidosis, as indicated. Assess for ketoacidosis regardless of presenting blood glucose levels and discontinue INPEFA if ketoacidosis is suspected. Monitor patients for resolution of ketoacidosis before restarting.
- Volume Depletion: Before initiating, correct volume status. Monitor for signs and symptoms of hypotension during therapy.
- Urosepsis and Pyelonephritis: Monitor for signs and symptoms during therapy and treat promptly.
- Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues: Lower dose of insulin or insulin secretagogue may be required.
- Necrotizing Fasciitis of the Perineum (Fournier's Gangrene): Monitor for pain, tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise. Discontinue INPEFA and treat urgently.
- Genital Mycotic Infections: Monitor and treat as appropriate.

➢ Adverse Reactions:

- Most common adverse reactions (incidence ≥ 5%) are urinary tract infection, volume depletion, diarrhea, and hypoglycemia.

Inpefa [package insert]. The Woodlands, TX; Lexicon Pharmaceuticals, Inc.; May 2023

Inpefa™(sotagliflozin)

➢ Drug Interactions:

- Digoxin: Monitor digoxin levels.
- Uridine 5'-diphospho-glucuronosyltransferase Inducers (e.g., rifampin): Sotagliflozin exposure is reduced. Consider monitoring of clinical status.
- Lithium: Monitor serum lithium concentrations.

➢ Specific Populations:

- Pregnancy: Advise females of the potential risk to a fetus especially during the second and third trimesters.
- Lactation: Inpefa is not recommended when breastfeeding.
- Geriatrics: Higher incidence of adverse reactions related to volume depletion.
- Renal Impairment: Higher incidence of adverse reactions related to volume depletion.

➢ Clinical Comparative Studies (within class):

- None

Inpefa [package insert]. The Woodlands, TX; Lexicon Pharmaceuticals, Inc.; May 2023

Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
VI. Endocrine and Metabolic Agents		
Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors ST		
Farxiga® Invokana® Jardiance®	Inpefa™ Invokamet® Invokamet® XR Segluromet® Steglatro® Synjardy® Synjardy® XR Trijardy® XR Xigduo® XR	**STEP THERAPY (ST)** • Requires trial with metformin with or without insulin prior to initiating SGLT2 therapy unless there is a contraindication, or the drug is being used for an FDA-approved Medicaid covered indication other than, or in addition to, Type 2 Diabetes.

Inpefa [package insert]. The Woodlands, TX; Lexicon Pharmaceuticals, Inc.; May 2023

Immunomodulators – Systemic Therapeutic Class Review

New York Medicaid
Drug Utilization Review Board Meeting
September 21, 2023

New Clinical Information

- New Drug Entity: Sotyktu™ (deucravacitinib)
- Humira Loss of Exclusivity
- New Indications
- Key Label revisions

Sotyktu™ (deucravacitinib)

Indications and Usage:

- Sotyktu is a tyrosine kinase 2 (TYK2) inhibitor indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
- Limitations of Use: Not recommended for use in combination with other potent immunosuppressants

Dosage and Administration:

- Recommended dosage is 6 mg orally once daily, with or without food.

Dosage Forms and Strengths:

- Tablets: 6 mg

Contraindications:

- Known hypersensitivity to deucravacitinib or any of the excipients

Sotyktu [package insert]. Princeton, NJ; Bristol-Myers Squibb; September 2022

Sotyktu™ (deucravacitinib)

Warnings and Precautions:

- Hypersensitivity: Hypersensitivity reactions such as angioedema have been reported. Discontinue if a clinically significant hypersensitivity reaction occurs.
- Infections: May increase the risk of infection. Avoid use in patients with active or serious infection. If a serious infection develops, discontinue until the infection resolves.
- Tuberculosis: Evaluate for TB prior to initiating treatment
- Malignancy: Malignancies including lymphomas were observed in clinical trials
- Rhabdomyolysis and elevated CPK.
- Laboratory Abnormalities: Periodically evaluate serum triglycerides. Evaluate liver enzymes at baseline and thereafter in patients with known or suspected liver disease.
- Immunizations: Avoid use with live vaccines.
- Potential Risks Related to JAK Inhibition: It is not known whether TYK2 inhibition may be associated with the observed or potential adverse reactions of JAK inhibition. Higher rates of all-cause mortality, including sudden cardiovascular death, major adverse cardiovascular events, overall thrombosis, deep venous thrombosis, pulmonary embolism, and malignancies (excluding non-melanoma skin cancer) were observed in patients treated with a JAK inhibitor compared to those treated with TNF blockers in rheumatoid arthritis (RA) patients. SOTYKTU is not approved for use in RA.

Adverse Reactions:

- Most common adverse reactions (≥1%) are upper respiratory infections, blood creatine phosphokinase increased, herpes simplex, mouth ulcers, folliculitis, and acne.

Drug Interactions:

- None reported

Sotyktu [package insert]. Princeton, NJ; Bristol-Myers Squibb; September 2022

Sotyktu™ (deucravacitinib)

Specific Populations:

- Sotyktu is not recommended in patients with severe hepatic impairment (Child-Pugh C).

Clinical Comparative Studies (within class):

- In PSO-1 and PSO-2, efficacy was assessed in 1,684 subjects randomized to either SOTYKTU (6 mg orally once daily), placebo, or apremilast (30 mg orally twice daily).
- The co-primary endpoints of these two studies only established safety and efficacy of Sotyktu compared to placebo.
- Comparisons with Sotyktu and apremilast were only derived as secondary endpoints and were made at the following time points:
  - at Week 16 and Week 24 (PSO-1 and PSO-2), the proportion of subjects who achieve PASI 75, PASI 90, and sPGA 0/1 with at least a 2-grade improvement from baseline
  - at Week 16 (PSO-1 and PSO-2), the proportion of subjects who achieved sPGA 0 and ss-PGA 0/1 with at least a 2-grade improvement from baseline (scalp)

Sotyktu [package insert]. Princeton, NJ; Bristol-Myers Squibb; September 2022

Humira Loss of Exclusivity

Low Concentration (50 mg) Formulations

Drug Name	Active Ingredient	Company	Launch	FDA Approval	Concentration	Citrate-Free	Interchangeable	Approved indications	Presentations				
									40 mg/0.8 ml PEN	40 mg/0.8 ml PFS	40 mg/0.8 ml Vial	20 mg/0.4 ml PFS	10 mg/0.2 ml PFS
Humira®	Adalimumab	Abbvie	LAUNCHED	12/31/2002	Low (50 mg)	✗	N/A	RA, JIA (2+), PsA, AS, CD(6+), UC(5+), Ps, HS (12+), UV (2+)	✓	✓	✓	✓	✓
Amjevita™	Adalimumab -atto	Amgen	LAUNCHED	9/23/2016	Low (50 mg)	✓	✗	RA, JIA (2+), PsA, AS, CD (6+), UC, Ps, HS, UV	✓	✓	✗	✓	✓
Hadlima™	Adalimumab -bwwd	Organon	LAUNCHED	7/23/2019	Low (50 mg)	✗	Seeking	RA, JIA (2+), PsA, AS, CD (6+), UC, Ps, HS, UV	✓	✓	✓	✗	✗
Cyltezo™	Adalimumab -adbm	Boehringer Ingelheim	LAUNCHED	8/25/2017	Low (50 mg)	✓	✓	RA, JIA (2+), PsA, AS, CD (6+), UC, Ps, HS, UV	✓	✓	✗	✓	✓
Yusimry	Adalimumab -aqvh	Coherus	LAUNCHED	12/17/2021	Low (50 mg)	✓	✗	RA, JIA (2+), PsA, AS, CD (6+), UC, Ps, HS, UV	✓	✓	✗	✗	✗
Hulio®	Adalimumab -fkjp	Mylan	LAUNCHED	7/6/2020	Low (50 mg)	✓	Seeking	RA, JIA (2+), PsA, AS, CD (6+), UC, Ps, HS, UV	✓	✓	✗	✓	✗
Idacio™	Adalimumab -aacf	Fresenius Kabi	LAUNCHED	12/13/2022	Low (50 mg)	✓	✗	RA, JIA (2+), PsA, AS, CD (6+), UC, Ps	✓	✓	✗	✗	✗
Abrilada™	Adalimumab -afzb	Pfizer	~10/1/2023	11/15/2019	Low (50 mg)	✓	Seeking	RA, JIA (2+), PsA, AS, CD (6+), UC, Ps, HS, UV	✓	✓	✓	✓	✓
Hyrimoz®	Adalimumab -adaz	Sandoz	N/A	10/30/2018	Low (50 mg)	✗	✗	RA, JIA (2+), PsA, AS, CD (6+), UC, Ps, HS	✓	✓	✗	✓	✓

Humira Loss of Exclusivity

High Concentration (100 mg) Formulations

Drug Name	Active Ingredient	Company	Launch	FDA Approval	Concentration	Citrate - Free	Interchangeable	Approved indications	Presentations and WAC/Unit					
									80 mg/0.8 ml PEN	80 mg/0.8 ml PFS	40 mg/0.4 ml PEN	40 mg/0.4 ml PFS	20 mg/0.2 ml PFS	10 mg/0.1 ml PFS
Humira®	Adalimumab	Abbvie	LAUNCHED	4/28/2017	High (100 mg)	✓	N/A	RA, JIA (2+), PsA, AS, CD(6+), UC(5+), Ps, HS (12+), UV (2+)	✓	✓	✓	✓	✓	✓
Hyrimoz®	Adalimumab -adaz	Sandoz	LAUNCHED	3/30/2023	High (100 mg)	✓	✗	RA, JIA (2+), PsA, AS, CD (6+), UC, Ps, HS	✓	✓	✓	✓	✓	✓
Hadlima	Adalimumab -bwwd	Organon	LAUNCHED	7/23/2019	High (100 mg)	✓	Seeking	RA, JIA (2+), PsA, AS, CD(6+), UC, Ps, HS, UV	✗	✗	✓	✓	✗	✗
Amjevita™	Adalimumab -atto	Amgen	TBD	8/14/2023	High (100 mg)	✓	Seeking	RA, JIA (2+), PsA, AS, CD (6+), UC, Ps, HS, UV	✓	✓	✓	✓	✓	✗
Yuflyma	Adalimumab -aaty	Celltrion	LAUNCHED	5/23/2023	High (100 mg)	✓	Seeking	RA, JIA (2+), PsA, AS, CD(6+), UC, Ps, HS	✗	✗	✓	✓	✗	✗

RA = Rheumatoid Arthritis, JIA = Juvenile Idiopathic Arthritis, PsA = Psoriatic Arthritis, AS = Ankylosing Spondylitis,
CD = Crohn's Disease, UC = Ulcerative Colitis, Ps = Psoriasis, HS = Hidradenitis Suppurativa, UV = Uveitis

New Indications

Dupixent® (dupilumab):

- FDA authorized use of single-dose, pre-filled pens in patients 6 months to < 12 years of age when administered by a caregiver (previously only the prefilled syringe was for use in this age range). The pens deliver 100 mg, 200 mg, and 300 mg; pediatric indications impacted are severe atopic dermatitis and severe asthma, which are approved for patients as young as 6 months and 6 years, respectively.
- FDA granted approval under Priority Review for the treatment of adults with prurigo nodularis at a recommended dose of 600 mg (two 300 mg injections) followed by 300 mg every other week by SC injection. Various sections of the label have been updated accordingly.

Rinvoq® (upadacitinib):

- FDA approved a new indication for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy. Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine). Recommended dosage for this new indication is 15 mg once daily.
- FDA approved for adults with moderately to severely active CD who have had an inadequate response or intolerance to ≥ 1 tumor necrosis factor blocker(s). After an induction dosage of 45 mg once daily for 12 weeks, the recommended maintenance dose is 15 mg once daily. Existing indications include RA, PsA, UC, AS, atopic dermatitis, & non-radiographic axial spondyloarthritis.

New Indications

- **Kevzara® (sarilumab):**
  - FDA approved for the treatment of adults with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate a steroid taper. Previously approved for RA. Dosage in PMR is 200 mg SC once every 2 weeks with a tapering course of steroids and as monotherapy following discontinuation of steroids.
- **Cibinqo™ (abrocitinib):**
  - FDA expanded indication to include pediatrics ≥ 12 years old with moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drugs products, including biologics, or when use of those therapies is inadvisable; previously approved only in adults. Recommended dose in adults and pediatrics is 100 mg orally once daily; after 12 weeks, if response is inadequate, may increase to 200 mg once daily; discontinue if 200 mg dose does not achieve adequate response.
- **Stelara® (ustekinumab):**
  - FDA approved for the treatment of pediatrics ≥ 6 years old with active PsA; previously, only approved in adults with active PsA. Recommended dosage in pediatrics is weight-based, given SC at weeks 0 and 4, then every 12 weeks thereafter. Ustekinumab is already indicated for moderate to severe active psoriasis in patients ≥ 6 years old and for moderate to severe CD and UC in adults.

Key Label Revisions

- Cosentyx (secukinumab) - Addition of eczematous eruptions to the Warnings and Precautions section and the addition of skin and subcutaneous tissue disorders to the Post-marketing Experience subsection; removal of all pertinent text related to the lyophilized powder; and an extension of the time allowed to store Cosentyx 75 mg/0.5 mL solution for injection in prefilled syringe at room temperature (e.g., in-use) for up to 4 days.
- Otezla (apremilast) - Clinical Trials Experience & Clinical Studies sections updated to include study data for treatment of moderate to severe plaque psoriasis affecting the genital area.
- Rinvoq (upadacitinib) - Data related to improvement in fatigue scores in patients with UC were added.
- Enbrel (etanercept) - Remove verbiage related to needle cover containing dry natural rubber. Enbrel devices are now made without natural rubber latex. Hypersensitivity subsection of Warnings and Precautions has been revised to reflect this.
- Tezspire (tezepelumab-ekko) - Includes information regarding serious cardiac ADR and MACE.
- Rinvoq (upadacitinib) - Updates to the following sections Warning/Precautions, ADRs, Drug Interactions, and Use in Specific Populations (pediatric use).
- Simponi (golimumab) - Instructions for SmartJect AutoInjector have been revised to remove the arm as an injection site option and to advise against pinching the skin during injection.
- Nucala (mepolizumab) - Removed the pregnancy exposure registry information from the pregnancy subsection.
- Stelara (ustekinumab) – Addition of ADR of hypersensitivity vasculitis to the postmarketing experience ADR subsection.

Immunomodulators – Systemic

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
IX. Immunologic Agents		
Immunomodulators – Systemic CC, ST		
Cosentyx® Dupixent® Enbrel® Fasenra® Humira® Nucala® Xolair®	Actemra® subcutaneous adalimumab-FKJP adalimumab-ADAZ Adbry™ Amjevita™ Cibinqo™ Cimzia® Cyltezo® Hadlima™ Hulio® (adalimumab-FKJP) Hyrimoz® (adalimumab-ADAZ) Idacio® Yuflyma® Yusimry™ Ilumya® Kevzara® Kineret® Olumiant® Orencia® subcutaneous Otezla® Rinvoq™ ER Siliq™ Simponi® Skyrizi® Skyrizi® On-Body Sotyktu™ Stelara® Taltz® Tezspire® pen Tremfya® Xeljanz® Xeljanz® XR	**CLINICAL CRITERIA (CC)** • Confirm diagnosis for FDA- or compendia-supported uses **STEP THERAPY (ST)** For indications not specified below • Trial of a non-specific anti-inflammatory drug such as an aminosalicylate or immunosuppressant, or a disease-modifying anti-rheumatic drug (DMARD) • Trial of a TNF inhibitor prior to treatment with a JAK inhibitor **INDICATION-SPECIFIC REQUIREMENTS:** • Asthma: – history and concurrent use of a corticosteroid • Nasal polyps: – history and concurrent use of an intranasal corticosteroid • Atopic dermatitis: – Trial with a topical prescription product for a duration of at least 3 months. – For JAK inhibitors: Trial of topical prescription product and systemic product for a combined duration of at least 6 months.

New York State Drug Utilization Review Board Meeting

September 21, 2023

Current NYRx Preferred Drug List for the 17 Drug Classes on the Agenda

NEW YORK STATE | Department of Health

Clinical Criteria for Non-Preferred Products

Non-Preferred Products remain available through the prior authorization process.

1. The preferred drug has been tried by the patient and has failed to produce the desired health outcome.

   Q: Has your patient experienced treatment failure with a preferred product?

2. The patient has tried the preferred drug and has experienced unacceptable adverse effects.

   Q: Has your patient experienced an adverse drug reaction with a preferred product?

3. The patient has been stabilized on a non-preferred drug and transition to the preferred drug would be medically contraindicated

   Q: Is there a documented history of successful therapeutic control with a non-preferred product and transition to a preferred product is medically contraindicated?

4. Other clinical indications for use of a non-preferred drug, which shall include consideration of the medical needs of special populations.

Medicaid Fee-for-Service Preferred Drug Program
1. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Non-Steroidal Anti-Inflammatory Drugs (NSAIDS)		
diclofenac 1% topical gel diclofenac sodium oral ibuprofen Rx (tablet, suspension) ibuprofen OTC (suspension) indomethacin ketorolac meloxicam (tablet) naproxen (tablet) piroxicam sulindac	Arthrotec® Celebrex® CC celecoxib CC Daypro® diclofenac epolamine patch (generic Flector®) diclofenac capsule diclofenac/misoprostol diclofenac potassium diclofenac potassium (generic Cambia®) diclofenac sodium ER diclofenac topical soln (generic Pennsaid®) diflunisal Duexis® Elyxyb™ F/Q/D etodolac etodolac ER Feldene® fenoprofen Flector® patch flurbiprofen ibuprofen/famotidine (generic Duexis®)	**CLINICAL CRITERIA (CC)** • Celebrex® (celecoxib) – one of the following criteria will not require PA – Over the age of 65 years – Concurrent use of an anticoagulant agent – History of GI Bleed/Ulcer or Peptic Ulcer Disease **FREQUENCY/QUANTITY/DURATION (F/Q/D)** • Elyxyb™ (celecoxib) – 4.8 mL bottle (120 mg) maximum quantity: 9 / 30 days

Medicaid Fee-for-Service Preferred Drug Program
1. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) (continued)

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Non-Steroidal Anti-Inflammatory Drugs (NSAIDS)		
	indomethacin ER ketoprofen ketoprofen ER ketorolac nasal spray (generic Sprix®) Licart™ meclofenamate mefenamic acid meloxicam (capsule) (generic Vivlodex®) Mobic® nabumetone Nalfon® Naprelan® naproxen (suspension) naproxen CR naproxen EC naproxen-esomeprazole naproxen sodium oxaprozin Pennsaid® Relafen® DS tolmetin Vimovo®	

Medicaid Fee-for-Service Preferred Drug Program

2. Opioids - Short Acting

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Opioids—Short-Acting[CC]		
butalbital/APAP/caffeine/codeine codeine codeine/APAP hydrocodone/APAP hydrocodone/ibuprofen Lortab® (elixir) morphine IR oxycodone/APAP tramadol tablet	Apadaz® benzhydrocodone/APAP butalbital compound/codeine butorphanol nasal spray dihydrocodeine/APAP/caffeine Dilaudid® hydromorphone levorphanol meperidine Nalocet® Nucynta® ST oxycodone oxymorphone pentazocine/naloxone Percocet® Prolate® (solution, tablet) Roxicodone® Seglentis® tramadol solution tramadol/APAP	**CLINICAL CRITERIA (CC)** • Limited to a total of 4 opioid prescriptions every 30 days. • Initial prescription for opioid-naïve patients limited to a 7-day supply. • PA required for initiation of opioid therapy for patients on established opioid dependence therapy. • PA required for use if ≥ 90 MME of opioid per day for management of non-acute pain (> 7 days) – Exception for diagnosis of cancer or sickle cell disease, or hospice program • PA is required for opioid-naïve patients for prescription requests ≥ 50 MME per day. • PA required for continuation of opioid therapy beyond an initial 7-day supply in patients established on gabapentin or pregabalin • PA required for initiation of opioid therapy in patients currently on benzodiazepine therapy • PA required for any codeine- or tramadol-containing products in pts < 12years • PA required for initiation of opioid therapy for patients on > 7 days established CNS stimulant therapy **STEP THERAPY (ST)** • Nucynta® (tapentadol IR) – Trial with tramadol and 1 preferred opioid before tapentadol immediate-release (IR) • For Non-opioid Pain management alternatives please visit: https://health.ny.gov/health_care/medicaid/program/opioid_management/docs/non_opioid_alternatives_to_pain_management.pdf *Exemptions from requirements for diagnosis of cancer, sickle cell disease, or hospice care

Medicaid Fee-for-Service Preferred Drug Program
3. Pulmonary Arterial Hypertension (PAH) Agents, Other – Oral

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Pulmonary Arterial Hypertension (PAH) Agents, Other-Oral		
ambrisentan (generic Letairis) bosentan tablets (generic Tracleer®)	Adempas® Letairis® Opsumit® Orenitram® ER (tablet, dosepack) Tracleer® tablet for suspension, tablet Uptravi®	

Medicaid Fee-for-Service Preferred Drug Program

4. Antimigraine Agents - Other

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Antimigraine Agents, Other[ST, F/Q/D]		
Ajovy® Emgality® Nurtec™ ODT	Aimovig® Emgality® 100mg syringe Qulipta™ Reyvow™ Ubrelvy™ Zavzpret™	**STEP THERAPY (ST)** **Acute treatment of migraine** • Trial of a product from the Antimigraine Agents-Triptan class **Prevention of migraine** • Trial of 2 FDA approved or compendia supported migraine prevention products from other drug classes **FREQUENCY/QUANTITY/DURATION (F/Q/D)** Aimovig 1 syringe/30 days Emgality 120 mg 2 syringes/30 days Emgality 100 mg 3 syringes/30 days Ajovy 3 syringes/90 days Reyvow 8 units/30 days Ubrelvy 16 units/30 days Nurtec™ ODT 24 units/40 days Qulipta 30 units/30 days Zavzpret® 8 units/30 days

Medicaid Fee-for-Service Preferred Drug Program

5. Antipsychotics - Injectable

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Antipsychotics-Injectable		
Abilify Maintena®	Abilify Asimtufii®	
Aristada®	Uzedy™	
Aristada Initio®		
fluphenazine decanoate		
Haldol® decanoate		
haloperidol decanoate		
Invega Hafyera™		
Invega Sustenna®		
Invega Trinza®		
Perseris™		
Risperdal Consta®		
Zyprexa Relprevv®		

Medicaid Fee-for-Service Preferred Drug Program

6. Antipsychotics - Second Generation

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Antipsychotics-Second Generation[CC,ST]		
aripiprazole tablet [DO] asenapine (generic Saphris®) clozapine lurasidone (generic Latuda®) olanzapine tablet [DO] quetiapine [F/Q/D] quetiapine ER [F/Q/D, DO] risperidone ziprasidone capsule	Abilify® tablet [DO] Abilify MyCite® aripiprazole solution aripiprazole ODT Caplyta™ clozapine ODT Clozaril® Fanapt® Geodon® Invega® [DO, F/Q/D] Latuda® [DO] Lybalvi™ Nuplazid® olanzapine ODT [DO] paliperidone ER [F/Q/D, DO] Rexulti® [DO] Risperdal® Saphris® Secuado® [F/Q/D] Seroquel® [F/Q/D] Seroquel XR® [DO, F/Q/D]	**DOSE OPTIMIZATION (DO)** • See Dose Optimization Chart for affected drugs and strengths **CLINICAL CRITERIA (CC)** • Clinical editing will allow patients currently stabilized on a non-preferred agent to continue to receive that agent without PA • Prior authorization is required when an oral SGA is utilized above the highest MDD according to FDA labeling. • Prior authorization is required for patients less than 21 years of age when there is concurrent use of 2 or more different oral antipsychotics for greater than 90 days. • Prior authorization is required for patients 21 years of age or older when 3 or more different oral second-generation antipsychotics are used for more than 180 days. • Confirm diagnosis of FDA-approved or compendia-supported indication • PA is required for initial prescription for beneficiaries younger than the drug-specific minimum age as indicated below: aripiprazole (Abilify®) 6 years aripiprazole (Abilify MyCite®) 18 years asenapine (Saphris®) 10 years asenapine (Secuado®) 18 years brexpiprazole (Rexulti®) 13 years cariprazine (Vraylar®) 18 years clozapine (Clozaril®, Versacloz®) 12 years iloperidone (Fanapt®) 18 years lumateperone (Caplyta™) 18 years lurasidone HCl (Latuda®) 10 years olanzapine (Zyprexa®) 10 years paliperidone ER (Invega®) 12 years pimavanserin (Nuplazid®) 18 years quetiapine fum. (Seroquel®, Seroquel XR®) 10 years risperidone (Risperdal®) 5 years ziprasidone HCl (Geodon®) 10 years

Medicaid Fee-for-Service Preferred Drug Program

- 6. Antipsychotics - Second Generation(continued)

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Antipsychotics-Second Generation[CC,ST]		
	Versacloz® Vraylar® DO Zyprexa® DO Zyprexa® Zydis	• Require confirmation of diagnosis that supports the concurrent use of a Second Generation Antipsychotic and a CNS Stimulant for patient < 18 years of age **STEP THERAPY (ST)** • For all Second Generation Antipsychotics used in the treatment of Major Depressive Disorder in the absence of other psychiatric comorbidities, trial with at least two different antidepressant agents is required **FREQUENCY/QUANTITY/DURATION (F/Q/D)** • asenapine (Secuado®) 7.6 mg/24 hours • lumateperone (Caplyta™) 42 mg capsules: Maximum 1 unit/day • paliperidone ER (Invega®) 1.5 mg, 3 mg, 9 mg tablets: Maximum 1 unit/day • paliperidone ER (Invega®) 6 mg tablets: Maximum 2 units/day • quetiapine/quetiapine ER (Seroquel®/Seroquel XR®): Minimum 100 mg/day; maximum 800 mg/day • quetiapine (Seroquel®): Maximum 3 units per day, 90 units per 30 days • quetiapine ER (Seroquel XR®) 150 mg, 200 mg: Maximum 1 unit/day, 30 units/30 days • quetiapine ER (Seroquel XR®) 50 mg, 300 mg, 400 mg: Maximum 2 units/day, 60 units/30 days

Medicaid Fee-for-Service Preferred Drug Program
7. Central Nervous System (CNS) Stimulants

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Central Nervous System (CNS) Stimulants[CC, F/Q/D]		
amphetamine salt combo IR (generic Adderall®) amphetamine salt combo ER (generic Adderall XR®) [DO] Concerta® [DO, BLTG] Daytrana® [BLTG] dexmethylphenidate (generic Focalin®) dexmethylphenidate ER [DO] (generic Focalin XR®) dextroamphetamine tablet methylphenidate solution (generic Methylin®) methylphenidate tablet (generic Ritalin®) methylphenidate ER (generic Aptensio® XR) Vyvanse® capsule, chewable [DO]	Adderall XR® [DO] Adzenys XR-ODT® amphetamine (generic Adzenys ER®) amphetamine (generic Evekeo®) Aptensio XR® armodafinil (generic Nuvigil®) Azstarys™ Cotempla® XR-ODT™ Desoxyn® Dexedrine® dextroamphetamine ER (generic Dexedrine®) dextroamphetamine solution (generic ProCentra®) dextroamphetamine tablet (generic Zenzedi®) Dyanavel XR® Evekeo® Evekeo® ODT Focalin® Focalin XR® [DO] Jornay PM™ methamphetamine (generic Desoxyn®) Methylin® methylphenidate (generic Daytrana®)	**CLINICAL CRITERIA (CC)** • Confirm diagnosis of FDA-approved, compendia-supported and Medicaid covered indication • Prior authorization is required for initial prescriptions for stimulant therapy for beneficiaries less than 3 years of age • Confirm diagnoses that support concurrent use of CNS Stimulant and Second Generation Antipsychotic agent for beneficiaries less than 18 years of age • Patient-specific considerations for drug selection include treatment of excessive sleepiness associated with shift work sleep disorder, narcolepsy, or as an adjunct to standard treatment for obstructive sleep apnea. • PA required for initiation of CNS Stimulant for patients currently on an opioid • PA required for initiation of CNS Stimulant for patients currently on a benzodiazepine **DOSE OPTIMIZATION (DO)** • See Dose Optimization Chart for affected drugs and strengths **FREQUENCY/QUANTITY/DURATION (F/Q/D)** • Quantity limits based on daily dosage as determined by FDA labeling • Quantity limits to include: – Short-acting CNS stimulants: not to exceed 3 dosage units daily with maximum of 90 days per strength (for titration) – Long-acting CNS stimulants: not to exceed 1 dosage unit daily with maximum of 90 days. Concerta 36mg and Cotempla XR-ODT 25.9mg,; not to exceed 2 units daily – Azstarys; not to exceed 1 dosage unit per day – Pitolisant (Wakix®): not to exceed 2 dosage units daily of the 17.8 mg tablets or 3 dosage units daily of the 4.45 mg tablets

Medicaid Fee-for-Service Preferred Drug Program
7. Central Nervous System (CNS) Stimulants (continued)

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Central Nervous System (CNS) Stimulants[CC, F/Q/D]		
	methylphenidate chewable tablet (generic Methylin®) methylphenidate CD [DO] methylphenidate ER 45 mg, 63 mg, 72 mg tablet methylphenidate ER (generic Concerta®, Ritalin LA®, Metadate®) modafinil (generic Provigil®) [DO] Mydayis™ Nuvigil® ProCentra® Provigil® [DO] QuilliChew ER™[DO] Quillivant XR® Relexxii® Ritalin® Ritalin LA® [DO] Sunosi™ Wakix® Xelstrym™ Zenzedi®	

Medicaid Fee-for-Service Preferred Drug Program

8. Multiple Sclerosis Agents

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Multiple Sclerosis Agents		
Avonex® Betaseron® Copaxone® 20 mg/mL[BLTG] dimethyl fumarate DR	Aubagio® Bafiertam™ Copaxone® 40 mg/mL Extavia® fingolimod (generic Gilenya®) Gilenya® glatiramer Kesimpta® Mavenclad® Mayzent® Plegridy® Ponvory™ F/Q/D Rebif® Rebif® Rebidose® Tascenso ODT™ Tecfidera® teriflunomide (generic Aubagio®) Vumerity® Zeposia® CC, ST	**CLINICAL CRITERIA (CC)** • Zeposia® (ozanimod): Confirm diagnosis for FDA- or compendia-supported use **STEP THERAPY (ST)** • Zeposia® (ozanimod): For an indication of Ulcerative Colitis -Trial of a non-specific anti-inflammatory drug such as an aminosalicylate or immunosuppressant, or a disease-modifying anti-rheumatic drug (DMARD), and; -Trial of a preferred systemic immunomodulator **FREQUENCY/QUANTITY/DURATION (F/Q/D)** • Ponvory™ (ponesimod) starter pack; maximum quantity is 14, no refills • Ponvory™ (ponesimod); maintenance limited to a 30-day supply

Medicaid Fee-for-Service Preferred Drug Program
9. Steroids, Topical - Medium Potency

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Steroids, Topical – Medium Potency		
mometasone furoate	Beser lotion betamethasone valerate foam clocortolone Cloderm® fluocinolone acetonide cream, ointment, solution flurandrenolide fluticasone propionate hydrocortisone butyrate cream, lotion, ointment, solution hydrocortisone valerate Locoid® Locoid Lipocream® Luxiq® Pandel® prednicarbate Synalar®	

Medicaid Fee-for-Service Preferred Drug Program
10. Steroids, Topical - High Potency

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Steroids, Topical – High Potency		
betamethasone dipropionate lotion, cream betamethasone dipropionate augmented cream betamethasone valerate cream, ointment triamcinolone acetonide	amcinonide ApexiCon-E® betamethasone dipropionate gel, ointment betamethasone dipropionate augmented lotion, ointment betamethasone valerate lotion desoximetasone diflorasone Diprolene® fluocinonide 0.1% cream (generic Vanos®) fluocinonide ointment, cream, gel, solution, emollient halcinonide cream (generic Halog®) Halog® cream, solution, ointment Kenalog® Topicort® triamcinolone spray Vanos®	

Medicaid Fee-for-Service Preferred Drug Program

11. Growth Hormones

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Growth Hormones[CC,CDRP]		
Genotropin® Norditropin®	Humatrope® Nutropin AQ® Omnitrope® Saizen® Skytrofa® Sogroya® Zomacton®	**CLINICAL DRUG REVIEW PROGRAM (CDRP)** • Prescribers or their authorized agents may call or submit a fax request for a PA for beneficiaries 18 years of age or older **CLINICAL CRITERIA (CC)** • Patient-specific considerations for drug selection include concerns related to use of a non-preferred agent for FDA-approved indications that are not listed for a preferred agent. • Confirm diagnosis of FDA-approved or compendia-supported indication

Medicaid Fee-for-Service Preferred Drug Program
12. Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors ST		
Farxiga® Invokana® Jardiance®	Inpefa™ Invokamet® Invokamet® XR Segluromet® Steglatro® Synjardy® Synjardy® XR Trijardy® XR Xigduo® XR	**STEP THERAPY (ST)** • Requires trial with metformin with or without insulin prior to initiating SGLT2 therapy unless there is a contraindication, or the drug is being used for an FDA-approved Medicaid covered indication other than, or in addition to, Type 2 Diabetes.

Medicaid Fee-for-Service Preferred Drug Program

13. Immunomodulators - Systemic

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Immunomodulators-Systemic [CC, ST]		
Cosentyx® Dupixent® Enbrel® Fasenra® Humira® Nucala® Xolair®	Actemra® subcutaneous adalimumab-FKJP adalimumab-ADAZ Adbry™ Amjevita™ Cibinqo™ Cimzia® Cyltezo® Hadlima™ Hulio® (adalimumab-FKJP) Hyrimoz® (adalimumab-ADAZ) Idacio® Yuflyma® Yusimry™ Ilumya® Kevzara® Kineret® Olumiant® Orencia® subcutaneous Otezla® Rinvoq™ ER Siliq™ Simponi® Skyrizi® Skyrizi® On-Body Sotyktu™ Stelara® Taltz® Tezspire® pen Tremfya® Xeljanz® Xeljanz® XR	**CLINICAL CRITERIA (CC)** • Confirm diagnosis for FDA- or compendia-supported uses **STEP THERAPY (ST)** For indications not specified below • Trial of a non-specific anti-inflammatory drug such as an aminosalicylate or immunosuppressant, or a disease-modifying anti-rheumatic drug (DMARD) • Trial of a TNF inhibitor prior to treatment with a JAK inhibitor **INDICATION-SPECIFIC REQUIREMENTS:** • Asthma: – history and concurrent use of a corticosteroid • Nasal polyps: – history and concurrent use of an intranasal corticosteroid • Atopic dermatitis: – Trial with a topical prescription product for a duration of at least 3 months. – For JAK inhibitors: Trial of topical prescription product and systemic product for a combined duration of at least 6 months.

Medicaid Fee-for-Service Preferred Drug Program
14. Sedative Hypnotics / Sleep Agents

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Sedative Hypnotics/Sleep Agents F/Q/D		
estazolam CC temazepam 15 mg, 30 mg CC zolpidem tablet CC	Ambien® CC Ambien CR® CC Belsomra® Dayvigo™ Doral® CC doxepin (generic Silenor®) Edluar® CC eszopiclone Halcion® CC Lunesta® DO quazepam CC (generic Doral®) Quviviq™ ramelteon (generic Rozerem®) Restoril® CC Rozerem® Silenor® temazepam 7.5 mg, 22.5 mg CC triazolam CC zaleplon zolpidem sublingual, capsule CC zolpidem ER CC	**DOSE OPTIMIZATION (DO)** • See Dose Optimization Chart for affected strengths **CLINICAL CRITERIA (CC)** • Zolpidem products: Confirm dosage is consistent with FDA labeling for initial prescriptions • Benzodiazepine Agents (estazolam, Halcion®, Restoril®, temazepam, triazolam): – Confirm diagnosis of FDA-approved or compendia-supported indication – PA required for initiation of benzodiazepine therapy in patients currently on opioid or oral buprenorphine therapy – PA required for any additional benzodiazepine prescription in patients currently on benzodiazepine therapy – PA required when greater than a 14-day supply of a benzodiazepine is prescribed for someone on a CNS stimulant **FREQUENCY/QUANTITY/DURATION (F/Q/D)** • Frequency and duration limits for the following products: – For non-zaleplon and non-benzodiazepine containing products: o 30 dosage units per fill/1 dosage unit per day/30 days – For zaleplon-containing products: o 60 dosage units per fill/2 dosage units per day/30 days – Duration limit equivalent to the maximum recommended duration: o 180 days for immediate-release zolpidem (Ambien®, Edluar®) products o 180 days for eszopiclone and ramelteon (Rozerem®) products o 180 days for lemborexant (Dayvigo™) o 168 days for zolpidem ER (Ambien CR®) products o 90 days for daridorexant (Quviviq™) o 90 days for suvorexant (Belsomra®) o 90 days for doxepin (Silenor®) o 30 days for zaleplon (Sonata®) products o 30 days for benzodiazepine agents (estazolam, Halcion®, Restoril®, temazepam, triazolam) for the treatment of insomnia **Additional/Alternate parameters:** • For patients naïve to non-benzodiazepine sedative hypnotics (NBSH): First-fill duration and quantity limit of 10 dosage units as a 10-day supply, except for zaleplon-containing products which the quantity limit is 20 dosage units as a 10-day supply

Medicaid Fee-for-Service Preferred Drug Program
15. Beta 2 Adrenergic Agents, Inhaled Short-Acting

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Beta2 Adrenergic Agents-Inhaled Short-Acting		
albuterol nebulizer solution Ventolin HFA® BLTG	albuterol HFA levalbuterol solution levalbuterol HFA ProAir® Digihaler™ ProAir® RespiClick Proventil HFA® Xopenex HFA®	

NEW YORK STATE | Department of Health

Medicaid Fee-for-Service Preferred Drug Program

16. Corticosteroids - Inhaled

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Corticosteroids-Inhaled F/Q/D		
Asmanex® Twisthaler Flovent Diskus® Flovent HFA® BLTG Pulmicort® Flexhaler	Alvesco® ArmonAir® Digihaler® Arnuity Ellipta® Asmanex® HFA fluticasone HFA (generic Flovent® HFA) QVAR RediHaler®	**FREQUENCY/QUANTITY/DURATION (F/Q/D)** Alvesco® 80 mcg 1 inhaler every 30 days Alvesco® 160 mcg 1 inhaler every 30 days. Up to 1 inhaler every 15 days with previous oral corticosteroid use. ArmonAir® Digihaler® 1 inhaler every 30 days Arnuity Ellipta 1 inhaler every 30 days Asmanex® 110 mcg 1 inhaler every 30 days Asmanex® 220 mcg (30 units) 1 inhaler every 30 days Asmanex® 220 mcg (60 units) 1 inhaler every 30 days. Up to 1 inhaler every 15 days with previous oral corticosteroid use. Asmanex® 220 mcg (120 units) 1 inhaler every 60 days. Up to 1 inhaler every 30 days with previous oral corticosteroid use. Asmanex® HFA 100 mcg 1 inhaler every 30 days Asmanex® HFA 200 mcg 1 inhaler every 30 days Flovent Diskus® 50 mcg, 100 mcg 1 diskus every 30 days Flovent Diskus® 250 mcg 1 diskus every 15 days. Up to 1 diskus every 7 days with previous oral corticosteroid use. Flovent HFA® 44 mcg, 110 mcg 1 inhaler every 30 days Flovent HFA® 220 mcg 1 inhaler every 30 days. Up to 1 inhaler every 15 days with previous oral corticosteroid use. Pulmicort 90 mcg 1 inhaler every 30 days Pulmicort 180 mcg 1 inhaler every 15 days QVAR® RediHaler™ 40 mcg 1 inhaler every 30 days QVAR® RediHaler™ 80 mcg 1 inhaler every 15 days

Medicaid Fee-for-Service Preferred Drug Program
17. Corticosteroids - Intranasal

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
Corticosteroids-Intranasal		
fluticasone	azelastine-fluticasone (generic Dymista®) Beconase AQ® CC Dymista® flunisolide mometasone Omnaris® QNASL® CC Ryaltris® Xhance™ Zetonna®	**CLINICAL CRITERIA (CC)** • Clinical consideration in regard to drug interactions will be given to patients with HIV/AIDs diagnosis or antiretroviral therapy in history

Medicaid Fee-for-Service Preferred Drug Program

END
PDP
REVIEW

DUR Webpage - http://www.health.ny.gov/health_care/medicaid/program/dur/index.htm

NEW YORK STATE | Department of Health

New York State Medicaid
Drug Utilization Review Program

NEW YORK STATE | Department of Health | Office of Health Insurance Programs

SUNY The State University of New York

Hepatitis C Virus– Utilization of Direct-Acting Antiviral Agents

September 21, 2023

NEW YORK STATE | Department of Health | Office of Health Insurance Programs

SUNY The State University of New York

Purpose

1. Review the utilization of the direct-acting antiviral (DAA) agents for the treatment of the chronic hepatitis C virus (HCV).

2. Evaluate the current clinical criteria for retreatment and determine if the clinical criteria can be removed.

Hepatitis C Guidance 2023 Update: AASLD-IDSA Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection

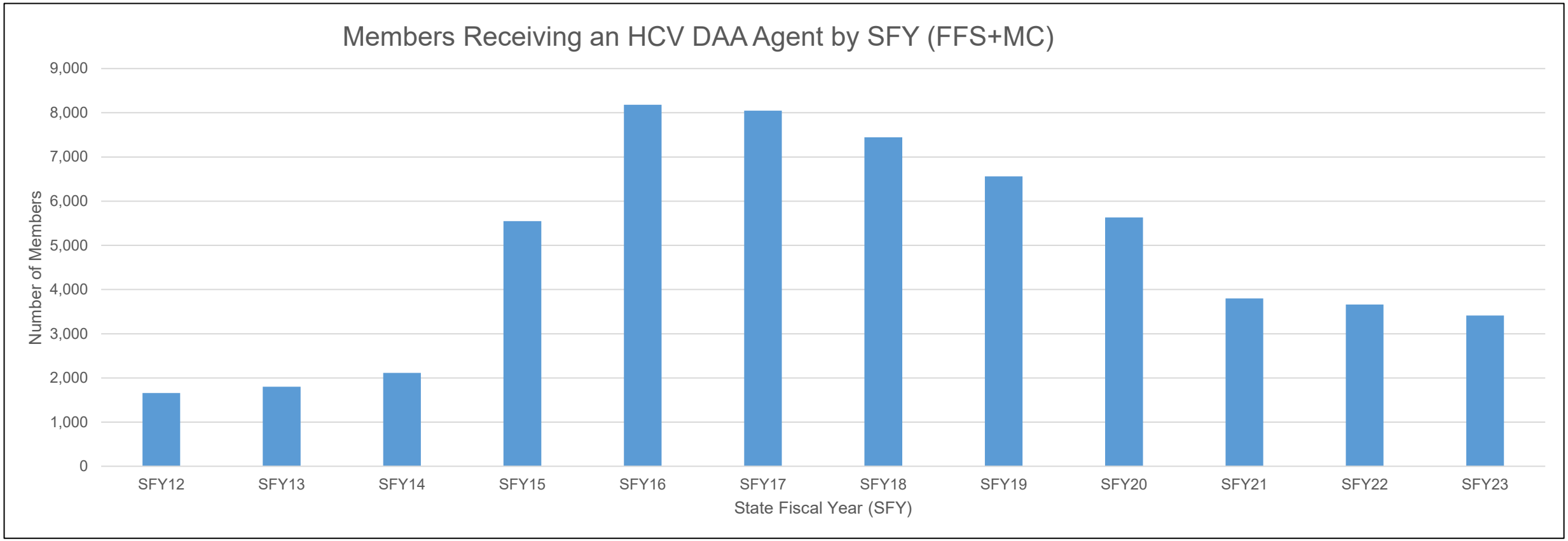
- A collaboration between the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA).
- The last guidance update was completed in 2020.

Key Points in HCV Guidance

- Universal HCV screening is recommended.
- The simplified HCV treatment algorithm now includes persons living with HIV.
- A new algorithm for incomplete treatment adherence is included with a key recommendation for persons who have missed ≤7 days of DAA therapy.
- HCV treatment is recommended for infected persons residing in jail or prison.
- Emerging data highlight the safety and efficacy of HCV DAA treatment in persons who have undergone solid organ transplantation.

DAA= direct-acting antiviral, HCV= hepatitis C virus, HIV= human immunodeficiency virus

Bhattacharya, D., Aronsohn, A., Price, J., & Lo Re, V. (2023). Hepatitis C Guidance 2023 Update: AASLD-IDSA Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. *Clinical Infectious Diseases*. https://doi.org/10.1093/cid/ciad319



April 2015

Viekira® Pak was excluded from disease prognosis and severity criteria.

May 2016

Disease prognosis and severity criteria were removed for preferred and nonpreferred HCV DAA agents.

August 2018

DAA prescriber experience training criteria were removed.

October 2020

Removal of PA for HCV DAA agents for persons not previously treated for HCV.

DAA= direct-acting antiviral, HCV= hepatitis C virus

Source: Medicaid Data Warehouse (MDW) Extract date: July 2023

Current HCV DAA Agents Clinical Criteria for Members Requiring Retreatment

Hepatitis C Agents – Direct Acting Antivirals		
Mavyret™ CC, F/Q/D ribavirin sofosbuvir/velpatasvir (gen Epclusa®) CC, F/Q/D Vosevi® CC, F/Q/D	Epclusa® CC, F/Q/D Harvoni® CC, F/Q/D ledipasvir/sofosbuvir (gen Harvoni®) CC, F/Q/D Sovaldi® CC, F/Q/D Viekira Pak® CC, F/Q/D Zepatier® CC, F/Q/D	**CLINICAL CRITERIA (CC)** • Confirm diagnosis of FDA-approved or compendia-supported indication • For patients being retreated require confirmation of patient readiness and adherence – Evaluation by using scales or assessment tools readily to determine a patient's readiness to initiate HCV treatment, specifically drug and alcohol abuse potential. Assessment tools are available to healthcare practitioners at: https://www.drugabuse.gov/nidamed-medical-health-professionals/screening-tools-resources/chart-screening-tools – OR https://prepc.org/. • The optional Hepatitis C Worksheet can be accessed at: https://newyork.fhsc.com/downloads/providers/NYRx_PDP_PA_Worksheet_Prescribers_HepC.pdf

For members requiring retreatment, the clinical criteria include the following:

1. Patient demographics
2. Confirmation of chronic hepatitis C diagnosis
    - •HCV genotypic testing
    - •Baseline HCV RNA PCR (viral load) testing
    - •Cirrhosis status
    - •Hepatic laboratory testing completed at baseline
    - •Screening for hepatitis B infection
    - •Negative pregnancy test (for patients receiving ribavirin)
3. HCV treatment history
4. Treatment readiness
5. Retreatment/ reinfection

NYRx, The Medicaid Pharmacy Program Preferred Drug List, Revised July 13, 2023. Accessed at NYRx, the Medicaid Pharmacy Program | Preferred Drug Program (fhsc.com).

Retreatment or Restart of an HCV DAA Agent

- Few patients were retreated on an HCV DAA agent within 365 days.
  - SFY 2022: 3.4% of members (FFS+MC)
    - 89.6% of members retreated in 365 days were restarted without completing an 8-week DAA regimen.
  - SFY 2023: 4.4% of members (FFS+MC)
    - 91.8% of members retreated in 365 days were restarted without completing an 8-week DAA regimen.

Eliminating HCV by Implementing Universal Screening

Public Health (PBH) CHAPTER 45, ARTICLE 21, TITLE 7: Required Offering of Hepatitis C Screening Testing:

- Adds the provision of a one-time HCV screening test for all individuals *younger* than 18 if there is evidence of risk.
- Requires an HCV screening test for all pregnant people during each pregnancy, which has been endorsed by the American College of Obstetrics and Gynecology.
- Ensures that when the HCV screening test is reactive, an HCV RNA (viral load) test must be performed to confirm the diagnosis of the current infection.

NYS Open Legislation | NYSenate.gov
NYS Hepatitis C Testing Law Frequently Asked Questions

NEW YORK STATE | Department of Health | Office of Health Insurance Programs

SUNY The State University of New York

Recommendations

1. Continue to monitor the utilization of the HCV DAA agents and report the results to the Drug Utilization Review Board.

2. Remove the clinical criteria associated with retreatment with an HCV DAA agent.

NEW YORK STATE | Department of Health

Update on the Management of Physician/Practitioner-Administered Drugs (PADs)

Drug Utilization Review (DUR) Board

Sept. 21, 2023

Overview

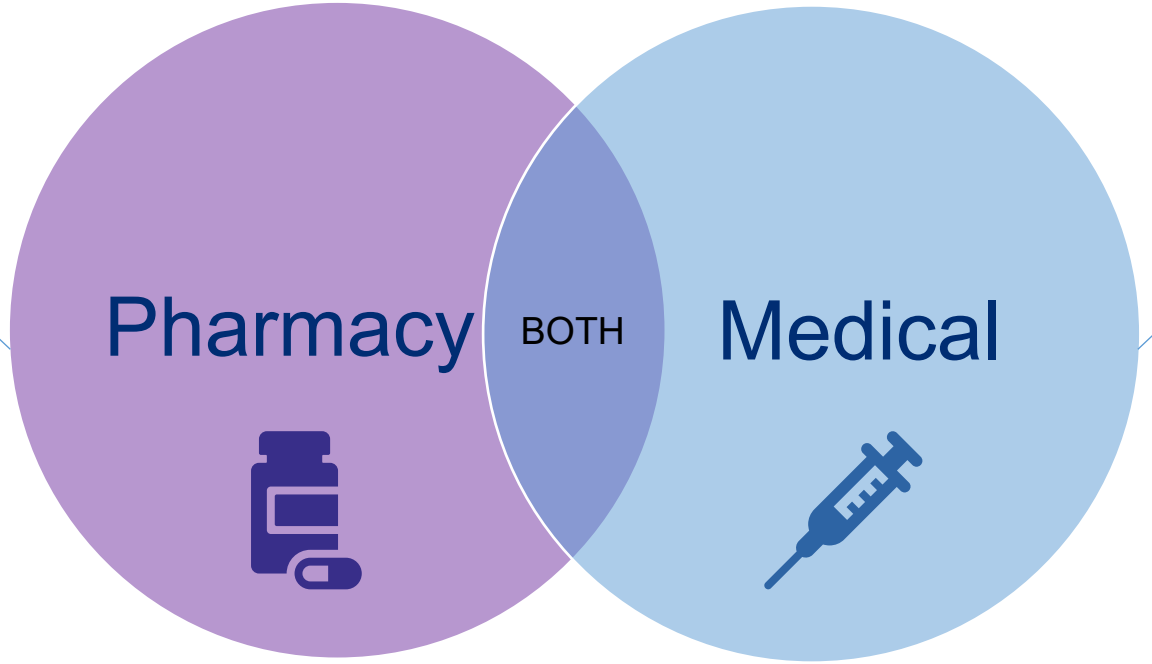
- Program Outline
- Program Vision and Benefits
- Roadmap
- Summary and Resources
- Q&A

Program Outline

Establishing Parity and Uniform Clinical Standards for Coverage of Drugs

2022-23 Enacted Medicaid Budget

- Typically self-administered
- Billed and dispensed by a pharmacy

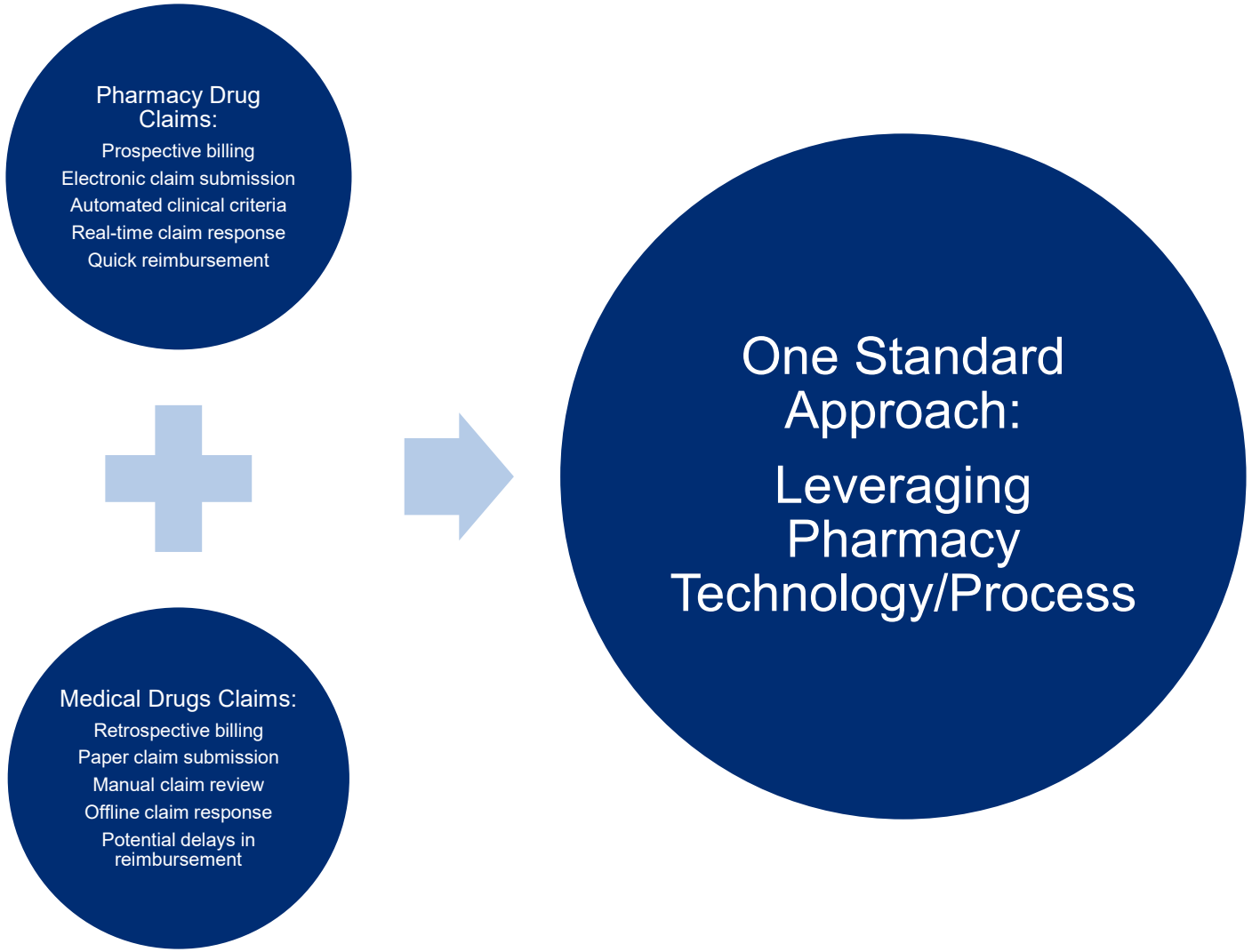


- Typically administered by a healthcare professional
- Billed by the provider

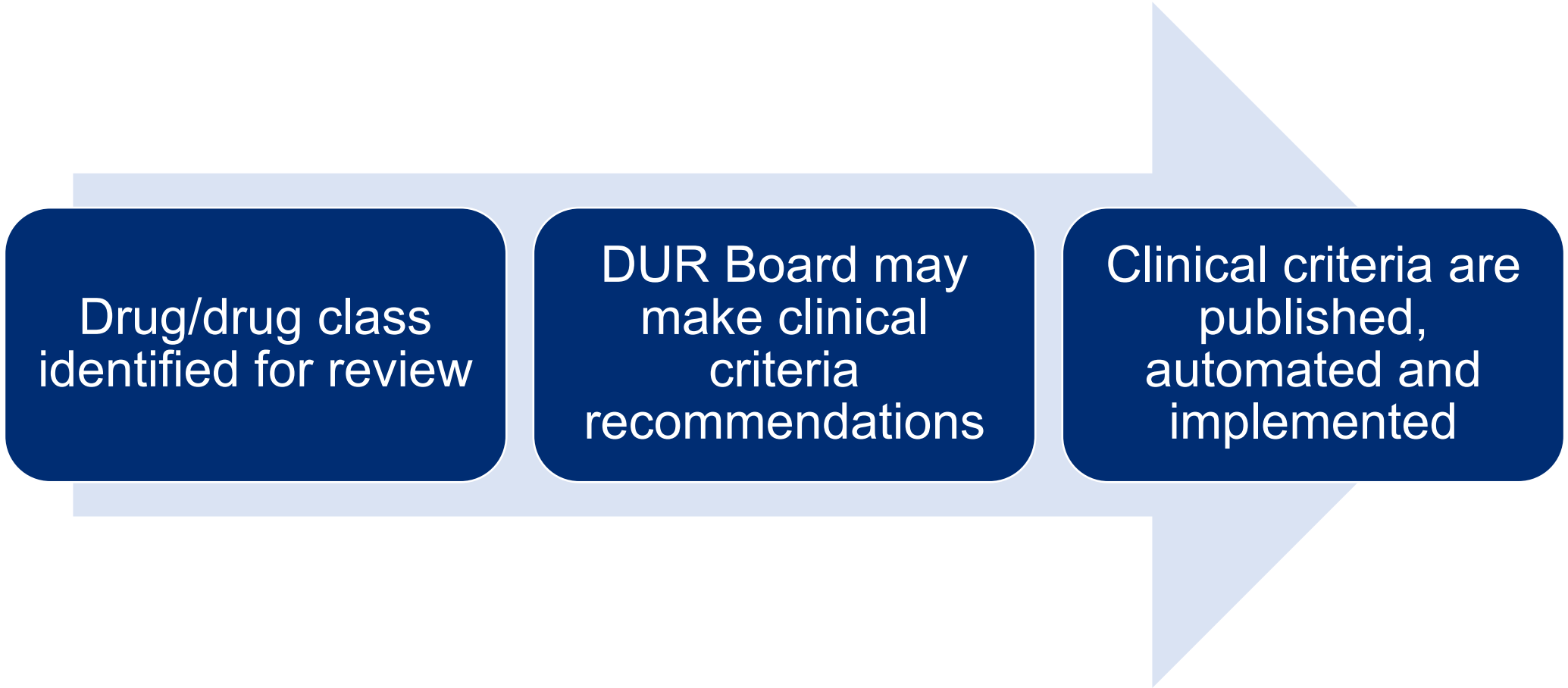
NEW YORK STATE | Department of Health

Program Vision and Benefits

Program Vision



Clinical Criteria Development



Drug Utilization Review Criteria

- Create a standard process for developing and implementing coverage criteria across the pharmacy and medical benefits

Revised: August 17, 2023

NYRx, the Medicaid Pharmacy Program Preferred Drug List

Preferred Drugs	Non-Preferred Drugs	Prior Authorization/Coverage Parameters
IX. Immunologic Agents		
Immunomodulators – Systemic CC, ST		
Cosentyx® Dupixent® Enbrel® Fasenra® Humira® Nucala® Xolair®	Actemra® subcutaneous adalimumab-FKJP adalimumab-ADAZ Adbry™ Amjevita™ Cibinqo™ Cimzia® Cyltezo® Hadlima™ Hulio® (adalimumab-FKJP) Hyrimoz® (adalimumab-ADAZ) Idacio® Yuflyma® Yusimry™ Ilumya® Kevzara® Kineret® Olumiant® Orencia® subcutaneous Otezla® Rinvoq™ ER Siliq™	**CLINICAL CRITERIA (CC)** • Confirm diagnosis for FDA- or compendia-supported uses **STEP THERAPY (ST)** For indications not specified below • Trial of a non-specific anti-inflammatory drug such as an aminosalicylate or immunosuppressant, or a disease-modifying anti-rheumatic drug (DMARD) • Trial of a TNF inhibitor prior to treatment with a JAK inhibitor **INDICATION-SPECIFIC REQUIREMENTS:** • Asthma: – history and concurrent use of a corticosteroid • Nasal polyps: – history and concurrent use of an intranasal corticosteroid • Atopic dermatitis: – Trial with a topical prescription product for a duration of at least 3 months. – For JAK inhibitors: Trial of topical prescription product and systemic product for a combined duration of at least 6 months.

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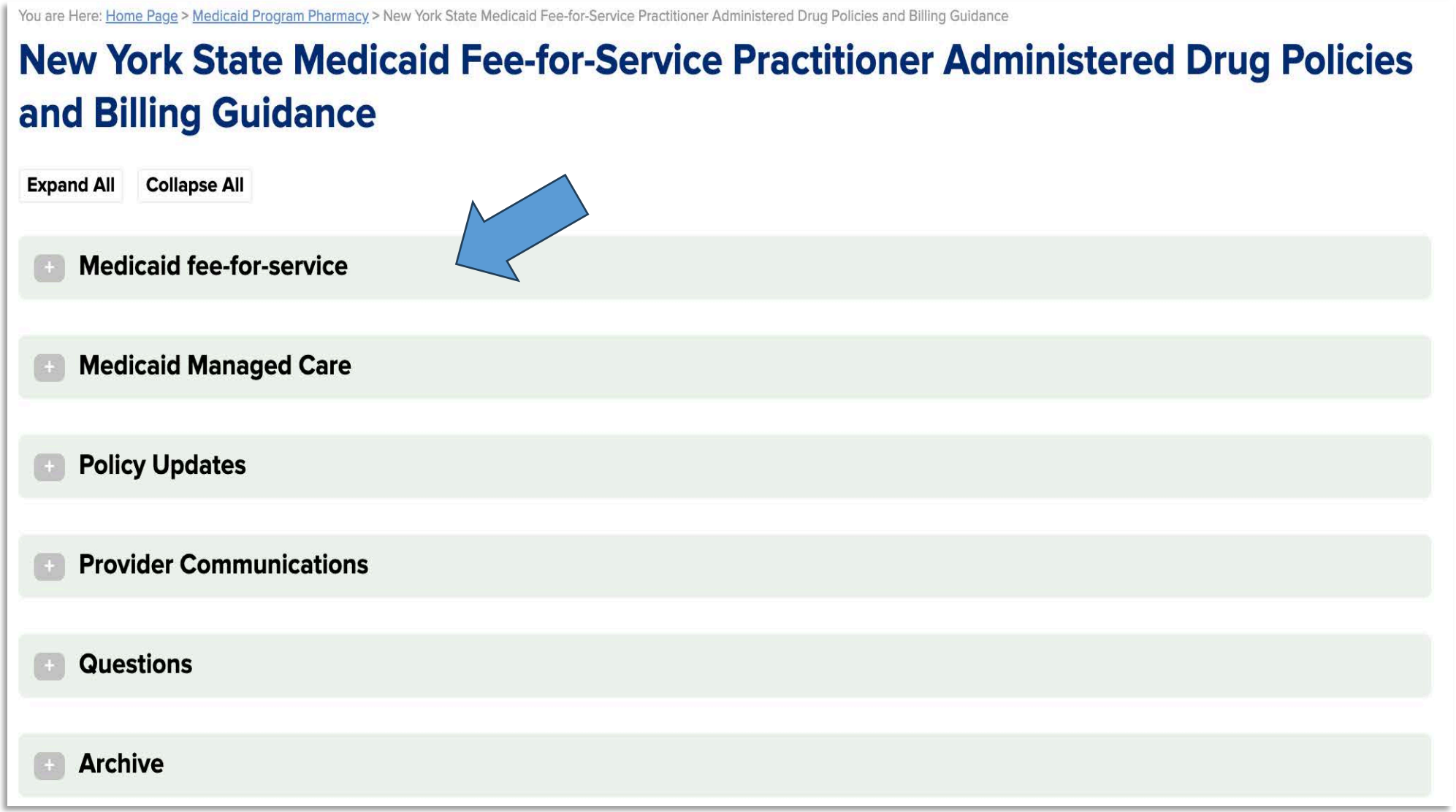

You are Here: Home Page > Medicaid Program Pharmacy > New York State Medicaid Fee-for-Service Practitioner Administered Drug Policies and Billing Guidance

New York State Medicaid Fee-for-Service Practitioner Administered Drug Policies and Billing Guidance

Expand All Collapse All

+ Medicaid fee-for-service

+ Medicaid Managed Care

+ Policy Updates

+ Provider Communications

+ Questions

+ Archive

https://www.health.ny.gov/health_care/medicaid/program/practitioner_administered/ffs_practitioner_administer.htm

NEW YORK STATE | Department of Health

- Modernize the way drug claims are submitted on the medical benefit
- Improve efficiency of the claims review process for drugs covered under the medical benefit and the respective clinical criteria

Medicaid fee-for-service

The document and web page found at the following links contain or access general information for providers participating in the New York State Medicaid fee-for-service (FFS) program on **policies and billing guidance for practitioner administered drugs:**

- Provider Manuals
- Medicine, Drugs and Drug Administration (See section: DRUGS ADMINISTERED OTHER THAN ORAL METHOD)

The following table contains links to guidance for providers participating in the Medicaid FFS program for specific drugs or drug classes that are practitioner administered. Policy specific for each listed drug or drug class is offered as a link to the latest pertinent *Medicaid Update* article. Some drugs or drug classes have Clinical Criteria Worksheets available. The Worksheets are designed to ensure complete claim documentation and outlines, step-by-step, the clinical as well as claim documentation requirements for drugs subject to clinical criteria. Legible, completed worksheets along with manufacturer invoices showing drug acquisition costs including all discounts, rebates and incentives can be submitted with each Health Care Finance Administration (HCFA) Claim Form (HCFA 1500). The associated invoices must be dated within 6 months prior to the dates of service and/or should include the expiration dates of the drugs.

Linked Guidance

Policy Specificity	Drug or Drug Class Name	Policy/Guidance	Clinical Criteria Worksheet	
			Fillable PDF* File	Microsoft Word™ File
Drug	Aducanumab-avwa (Aduhelm®)	October 2022 November 2022	Aduhelm PDF	Aduhelm Word
Drug Class	Infliximab products	October 2022 November 2022	Infliximab PDF	Infliximab Word
Drug	AbobotulinumtoxinA (Dysport®)	October 2022 November 2022	Dysport PDF	Dysport Word
Drug	IncobotulinumtoxinA (Xeomin®)	October 2022 November 2022	Xeomin PDF	Xeomin Word
Drug	OnabotulinumtoxinA (Botox®)	October 2022 November 2022	Botox PDF	Botox Word
Drug	RimabotulinumtoxinB (Myobloc®)	October 2022 November 2022	Myobloc PDF	Myobloc Word
Drug	Vedolizumab (Entyvio®)	October 2022 November 2022	Entyvio PDF	Entyvio Word
Drug	Esketamine (Spravato®) Nasal Spray	August 2022	Spravato PDF	Spravato Word
Drug Class	Viscosupplementation with Hyaluronan or Derivative	April 2022	Viscosupplementation PDF	Viscosupplementation Word
Drug	Goserlin implant (Zoladex®)	March 2022	Zoladex PDF	Zoladex Word

NEW YORK STATE | Department of Health

Program Benefits

- **Providers:**
  - Increased transparency into coverage criteria
  - Ability to secure authorization prior to drug administration
  - Decreased administrative burden- streamlined claim submission process
  - Expedited reimbursement
- **Patients:**
  - Improved safety checks will ensure medication use is appropriate and in line with current recommendations

Roadmap

Roadmap

Clinical criteria recommendations for PADs may not be fully implemented until go live date

Summary and Resources

Resources

DOH Medicaid Update:
https://www.health.ny.gov/health_care/medicaid/program/update/main.htm

eMedNY LISTSERV:
https://www.emedny.org/Listserv/eMedNY_Email_Alert_System.aspx

FFS Practitioner Administered Drug Policies and Billing Guidance Website:
https://www.health.ny.gov/health_care/medicaid/program/practitioner_administered/ffs_practitioner_administer.htm

FFS Physician Manual:
https://www.emedny.org/ProviderManuals/Physician/index.aspx

NEW YORK STATE | Department of Health

Summary

- Uniform clinical standards for coverage of drugs will modernize the process for the review of drugs covered under the medical benefit
- Existing tools and processes utilized in the pharmacy benefit will be leveraged
- Clinical criteria will be established for PADs and will continue to be brought to the DUR Board for review when needed
- More information on timeline and details regarding implementation will be provided as they become available

Questions & Answers

NEW YORK STATE | Department of Health

Drug Utilization Review (DUR) Board Meeting
September 21, 2023

Update to the Procedures for DUR Board Member Videoconferencing

Procedures for Member Videoconferencing

On April 9, 2022, Governor Hochul signed Chapter 56 of the Laws of 2022 relating to the New York State budget for the 2022-2023 state fiscal year.

Included in the bill is an amendment to the Open Meetings Law (OML) §103-a that expands the use of videoconferencing by public bodies to conduct open meetings, under extraordinary circumstances, regardless of a declaration of emergency. The provision is set to expire July 1, 2024.

Chapter 56 of the Laws of 2022 Guidance Document

Procedures for Member Videoconferencing

The DUR Board may pass a resolution and adopt procedures to satisfy the requirement of Public Offers Law (POL) §103-a(2)(b), which permits members of a public body to participate in meetings by videoconferencing from a non-public location under extraordinary circumstances.

- Open Meetings Law (OML)
  - §103-a. Videoconferencing by public bodies
    - Model Resolution and Model Procedures for member videoconferencing pursuant to Public Officers Law §103-a Chapter 56 of the Laws of 2022 Guidance Document

Procedures for Member Videoconferencing

Open Meetings Law (OML)

The Open Meetings Law applies to "public bodies." That term is defined to include entities consisting of two or more people who conduct public business and perform a governmental function for New York State, for an agency of the state or for public corporations, such as cities, counties, towns, villages and school districts including committees and subcommittees of these entities. Consequently, city councils, town boards, village boards of trustees, school boards, commissions, legislative bodies, and committees and subcommittees consisting of members of those groups fall within the coverage of the Law.

Open Meetings Law | Open Government (ny.gov)

Open Meetings Law FAQs

Procedures for Member Videoconferencing

Open Meetings Law (OML)

§103-a. Videoconferencing by public bodies

2. A public body may, in its discretion, use videoconferencing to conduct its meetings pursuant to the requirements of this article provided that a minimum number of members are present to fulfill the public body's quorum requirement in the same physical location or locations where the public can attend, and the following criteria are met:

(a) the governing board of a county, city, town or village has adopted a local law, or a public body has adopted a resolution, or the senate and assembly have adopted a joint resolution, following a public hearing, authorizing the use of videoconferencing: (i) for itself and its committees or subcommittees; or, (ii) specifying that each committee or subcommittee may make its own determination; (iii) provided however, each community board in a city with a population of one million or more shall make its own determination;

(b) the public body has established written procedures governing member and public attendance consistent with this section, and such written procedures shall be conspicuously posted on the public website of the public body;

Procedures for Member Videoconferencing

Open Meetings Law (OML)

§103-a. Videoconferencing by public bodies

(c) members of the public body shall be physically present at any such meeting unless such member is unable to be physically present at any such meeting location due to extraordinary circumstances, as set forth in the resolution and written procedures adopted pursuant to paragraphs (a) and (b) of this subdivision, including disability, illness, caregiving responsibilities, or any other significant or unexpected factor or event which precludes the member's physical attendance at such meeting. Notwithstanding the in person quorum requirements set forth in this subdivision, the public body may determine, through its written procedures governing member and public attendance established pursuant to and consistent with this section, to allow for any member who has a disability as defined in section two hundred ninety-two of the executive law, where such disability renders such member unable to participate in-person at any such meeting location where the public can attend, to be considered present for purposes of fulfilling the quorum requirements for such public body at any meetings conducted through videoconferencing pursuant to this section, provided, however, that the remaining criteria set forth in this subdivision are otherwise met; and provided, further, that the public body maintains at least one physical location where the public can attend such meeting;

Procedures for Member Videoconferencing

Open Meetings Law (OML)

§103-a. Videoconferencing by public bodies

(d) except in the case of executive sessions… the public body shall ensure that members of the public body can be heard, seen, and identified, while the meeting is being conducted, including but not limited to any motions, proposals, resolutions, and any other matter formally discussed or voted upon;

(e) the minutes of the meeting involving videoconferencing shall include, which, if any, members participated remotely and shall be available to the public pursuant to section one hundred sox of this article;

(f) if videoconferencing is used to conduct a meeting, the public notice for the meeting shall inform the public that videoconferencing will be used, where the public can view and/or participate in such meeting, where required documents and records will be posted or available, and identify the physical location for the meeting where the public can attend;

Procedures for Member Videoconferencing

Open Meetings Law (OML)

§103-a. Videoconferencing by public bodies

(g) the public body shall provide that each meeting conducted using videoconferencing shall be recorded and such recordings posted or linked on the public website of the public body within five business days following the meeting and shall remain so available for a minimum of five years thereafter. Such recording shall be transcribed upon request;

(h) If videoconferencing is used to conduct a meeting, the public body shall provide the opportunity for members of the public to view such meeting via video, and to participate in proceeding via videoconference in real time where public comment or participation is authorize and shall ensure that videoconferencing authorizes the same public participation or testimony as in person participation or testimony; and

(i) a local public body electing to utilize videoconferencing to conduct its meetings must maintain an official website.

Procedures for Member Videoconferencing

Open Meetings Law (OML) –Resources

Member videoconferencing pursuant to Public Officers Law § 103-a
Chapter 56 of the Laws of 2022 Guidance Document

The Guidance Document contains Questions and Answers, a Model Resolution, and a Model Procedure.

Open Meetings Law | Open Government (ny.gov)

The website for the Committee on Open Government -Open Meetings contains the Law Text, Advisory Opinions, Case Law Summaries, Model Rules for Public Bodies, Publications and Frequently Asked Questions.