The Medicaid Drug Utilization Review (DUR) program, inclusive of the DUR Board, helps to ensure that pharmaceutical therapy is appropriate, medically necessary, and not likely to result in adverse medical consequences. The following table contains clinical criteria and coverage parameters for certain Practitioner Administered Drugs (PADs). For PADs not listed below, coverage is in accordance with FDA-approved or compendia supported, and Medicaid covered indications.

Drug / Drug Class	Clinical Criteria / Coverage Parameters	Clinical Criteria Worksheets for the Fee-for-Service (FFS) Program
Botulinum Toxin Agents onabotulinumtoxinA (Botox®) abobotulinumtoxinA (Dysport®) rimabotulinumtoxinB (Myobloc®) incobotulinumtoxinA (Xeomin®)	Confirm diagnosis of Food and Drug Administration (FDA)-approved or compendia supported indication and Medicaid covered indication. Trial of glycopyrrolate for chronic sialorrhea (excludes patients with Parkinson's disease and other neurogenerative diseases). Trial of two oral agents FDA-approved or compendia-supported for prevention of migraine for treatment of headache prevention in patients with chronic migraine. Trial of antimuscarinic agent or beta-3-adrenoceptor agonist for overactive bladder.	Botox® Dysport® Myobloc® Xeomin®

Drug / Drug Class	Clinical Criteria / Coverage Parameters	Clinical Criteria Worksheets for the Fee-for-Service (FFS) Program
betibelogene autotemcel (Zynteglo™) ^*	Confirm diagnosis of FDA-approved or compendia supported indication and Medicaid covered indication. For members with a diagnosis of transfusion-dependent beta-thalassemia: the patient is a candidate for allogenic hematopoietic cell transplantation, but ineligible due to the absence of a donor; and the patient is less than or equal to (≤) fifty years of age. If the patient is less than (<) five years of age, the patient weight must be greater than or equal to (≥) six kilograms. Confirmation of FDA-approved or compendia supported indication and Medicaid covered indication.	Zynteglo™
Chimeric Antigen Receptor (CAR) T-cell Therapy	Confirm diagnosis of FDA-approved or compendia supported indication and Medicaid covered indication.	N/A

Drug / Drug Class	Clinical Criteria / Coverage Parameters	Clinical Criteria Worksheets for the Fee-for-Service (FFS) Program
Duchenne Muscular Dystrophy (DMD) casimersen (Amondys 45™) eteplirsen (Exondys 51™) viltolarsen (Viltepso™) golodirsen (Vyondys 53™)	Confirm diagnosis of FDA-approved or compendia supported indication and Medicaid covered indication: documentation of genetic testing must confirm the DMD gene mutation of the patient is amenable to exon 45, 51, or 53 skipping; documentation must confirm a stable dose of corticosteroids prior to starting therapy or a documented reason not to be on corticosteroids; documentation indicates kidney function testing prior to starting therapy (except for eteplirsen); *and* patient is not concurrently being treated with another exon skipping therapy for DMD.	Duchenne Muscular Dystrophy

Drug / Drug Class	Clinical Criteria / Coverage Parameters	Clinical Criteria Worksheets for the Fee-for-Service (FFS) Program
elivaldogene autotemecel (Skysona®)	Confirm diagnosis of FDA-approved or compendia supported indication and Medicaid covered indication. The patient is a candidate for hematopoietic stem cell transplant (HSCT), but ineligible due to the absence of a donor. The patient does not have human immunodeficiency virus (HIV) or human T-lymphotropic virus (HTLV). The patient is not utilizing anti-retroviral drugs at least one month prior to initiating medications for stem cell mobilization and until all cycles of apheresis are completed.	Skysona®

Drug / Drug Class	Clinical Criteria / Coverage Parameters	Clinical Criteria Worksheets for the Fee-for-Service (FFS) Program
esketamine nasal spray (Spravato®)	Confirm diagnosis of FDA-approved or compendia supported indication and Medicaid covered indication. Before initiating Spravato® (esketamine) nasal spray, prescribers must attest that they have obtained a baseline score using a validated clinical assessment tool for depression [e.g., Hamilton Depression Rating Scale (HAMD-17), Quick Inventory of Depressive Symptomatology (QIDS-C16C), Montgomery-Asberg Depression Rating Scale (MADRS)]. Trial of at least two oral antidepressants prior to Spravato® (esketamine) nasal spray when used for Treatment Resistant Depression. After the initiation of Spravato® (esketamine) nasal spray therapy, every six months prescribers must attest that Spravato® (esketamine) nasal spray has resulted in an improvement of depressive symptoms (from baseline) using the same baseline clinical assessment tool for depression [e.g., Hamilton Depression Rating Scale (HAMD-17), Quick Inventory of Depressive Symptomatology (QIDS-C16C), Montgomery-Asberg Depression Rating Scale (MADRS)].	Spravato®
etranacogene dezaparvovec-drlb (Hemgenix®)	Confirm diagnosis of FDA-approved or compendia supported indication and Medicaid covered indication. The patient must have a confirmation of moderately severe to severe, congenital hemophilia B. The patient does not have a history of factor IX inhibitors. The patient does not have a positive factor IX inhibitor test.	Hemgenix®

Drug / Drug Class	Clinical Criteria / Coverage Parameters	Clinical Criteria Worksheets for the Fee-for-Service (FFS) Program
goserlin implant (Zoladex®)	Coverage of Zoladex® will continue to be provided for Medicaid members who are unable to obtain the medication through the Patient Assistance Program (PAP) and when used under the following conditions: for a FDA approved indication for which there are no alternative options *and;* as a continuation of established therapy if another gonadotropin-releasing hormone (GnRH) product has been tried and failed or if transition to another GnRH is medically contraindicated.	Zoladex®

Drug / Drug Class	Clinical Criteria / Coverage Parameters	Clinical Criteria Worksheets for the Fee-for-Service (FFS) Program
Infliximab Agents	infliximab (Remicade®), infliximab-abda (Renflexis®), infliximab-axxq (Avsola®), and infliximab-dyyb (Inflectra®) Confirm diagnosis of FDA-approved or compendia supported indication and Medicaid covered indication. A trial of a conventional agent, disease-modifying anti-rheumatic drug (DMARD) or tumor necrosis factor inhibitor (TNFi), Food and Drug Administration (FDA)-approved for self-administration prior to initiation of infliximab, in accordance with FDA package labeling or compendia-supported use. vedolizumab (Entyvio®) Confirm diagnosis of FDA-approved or compendia supported indication and Medicaid covered indication. A trial of a conventional agent, DMARD or TNFi, prior to initiation of vedolizumab in accordance with FDA package labeling or compendia-supported use.	Infliximab Entyvio®
nusinersen (Spinraza®)	Confirm diagnosis of FDA-approved or compendia supported indication and Medicaid covered indication The patient must not have advanced disease (e.g., complete limb paralysis or permanent ventilator dependence)	Spinraza®

Drug / Drug Class	Clinical Criteria / Coverage Parameters	Clinical Criteria Worksheets for the Fee-for-Service (FFS) Program
onasemenogene aberparvovec-xioi (Zolgensma®)	In accordance with FDA indications, FFS will reimburse Zolgensma® for one treatment per person for their lifetime when the following criteria are met: The patient must have a confirmed diagnosis of SMA with bi-allelic mutations in the SMN1 gene; The patient must have three (3) copies or less of the SMN2 gene; The patient must be less than two (2) years of age; For neonatal patients born prematurely, full-term corrected gestational age (40 weeks) must be reached The patient must have a baseline anti-AAV9 antibody titer of ≤ 1:50 prior to administration; and The patient must not have advanced disease (i.e., complete limb paralysis, permanent ventilation dependence). *Note: Permanent ventilator dependence is defined as requiring invasive ventilation (tracheostomy) or respiratory assistance for 16 or more hours per day (including noninvasive ventilator support) continuously for 14 or more days in the absence of an acute reversible event, excluding perioperative ventilation.*	Zolgensma®

Drug / Drug Class	Clinical Criteria / Coverage Parameters	Clinical Criteria Worksheets for the Fee-for-Service (FFS) Program
Viscosupplementation	Have a diagnosis of either: Arthropathy – disorder of shoulder, or Subacromial impingement, syndrome of the shoulder	Viscosupplementation
Sickle Cell Disease exagamglogene autotemcel (Casgevy™)^* lovotibeglogene autotemcel (Lyfgenia ®)^*	Confirm diagnosis of FDA-approved or compendia supported indication and Medicaid covered indication.	N/A

^ The drug is carved out of the FFS inpatient rate.
* The drug is carved out of Managed Care. Approval for treatment related medical care will be determined by the Managed Care Plan with notification to the Department of such approval.