TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Onasemnogene abeparvovec-brve (Itvisma)	**CRITERIA ID:** TX.CC.PHAR.58
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 07/01/2026	**PRODUCT(S):** STAR, STAR+PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: N/A	**REGULATOR MOST RECENT APPROVAL DATE(S):** N/A

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for onasemnogene abeparvovec-brve (Itvisma).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a non-risk based (NRB) payment drug and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

The procedure code J3405 (used for Itvisma) will be limited to one approval per lifetime, by any provider.

This medication is designated by HHSC as a high-cost clinician-administered drug (HCCAD), allowing separate reimbursement for inpatient use. When inpatient use is required, the drug may be billed on a separate outpatient claim or through specialty pharmacy billing, when available.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
CPS = Centene Pharmacy Services
NRB = Non-Risk Based
SHP = Superior HealthPlan

UM = Utilization Management

POLICY:
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of onasemnogene abeparvovec-brve (Itvisma); procedure code: J3405.

Description/Mechanism of Action:
Onasemnogene abeparvovec-brve (Itvisma) is an adeno-associated virus (AAV) vector-based gene therapy

FDA Approved Indications:
Itvisma is an adeno-associated virus (AAV) vector-based gene therapy indicated for the treatment of spinal muscular atrophy (SMA) in adult and pediatric patients 2 years of age and older with confirmed mutation in SMN1 gene.

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria:

A. Spinal muscular atrophy (SMA):

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. The client is 2 years of age or older.
3. The client has a confirmed diagnosis of SMA (diagnosis codes: G12.0, G12.1, G12.25, G12.8, or G12.9).
4. Documentation of SMA diagnostic test confirming SMN1 deletion, or the client has historical documentation of a prior test.
5. Documentation supporting any of the following mutations or deletion of genes in chromosome 5q:
   a. Homozygous gene deletion of the SMN1 gene (e.g., absence of SMN1 gene).
   b. Homozygous mutation of the SMN1 gene (e.g., biallelic mutation of exon 7).
   c. Compound heterozygous mutation in the SMN1 gene (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2])
6. The client has a baseline documentation of AAV9 antibody titer of 1:50 or lower as determined by ELISA binding immunoassay.
7. Documentation that overall baseline health status of the client is stable as confirmed by the following:
   a. Complete blood count, liver function, and creatinine are within normal limits.
   b. No signs or symptoms of active infection.
8. Provider attestation of the following:
   a. The client's liver function must be examined by clinical examination and laboratory testing (e.g., hepatic aminotransferases (aspartate aminotransferase (AST) and alanine aminotransferase (ALT), total bilirubin, and prothrombin time) prior to infusion of Itvisma.
   b. Systemic corticosteroids must be administered prior to and after the administration of the drug.

c. Provider will continue to monitor client's liver function for at least 3 months after the infusion of Itvisma.

9. Provider attestation to counseling female clients of childbearing age regarding the use of an effective method of contraception to prevent pregnancy during treatment and to refrain from egg donation for up to six months after dose administration of Itvisma therapy. Male clients should refrain from fathering a child or donating sperm for 3 months following therapy.
10. If Spinraza or Evrysdi have been previously prescribed, the prescriber must provide documentation of one of the following prior to switching to Itvisma therapy:
    a. Evidence of clinical deterioration (e.g., decreased physical function and motor skill/function test scores) while on Spinraza or Evrysdi therapy.
    b. Prescriber's attestation that Spinraza or Evrysdi therapy has been discontinued.
11. Provider attestation that client has not previously received Itvisma, Zolgensma, or any other gene therapy for SMA.
12. Provider attestation to monitor the following after administering Itvisma:
    a. Monitor clients for signs of hepatotoxicity, thrombocytopenia, peripheral sensory neuropathy, and thrombotic microangiopathy.
    b. Monitor for elevated cardiac troponin I levels.

Note: Itvisma will not be a benefit for clients with a tracheostomy or invasive ventilator support.

Approval duration: 12 months (Only 1 dose per lifetime will be provided on this drug regardless of Provider).

REFERENCES:
Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS:

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy	N/A	07/01/2026