Onasemnogene Abeparvovec (Itvisma) – PA Criteria

HCPC: J3405

Onasemnogene Abeparvoved (Ivtisma) is a recombinant adeno-associated virus vector-based gene therapy that is indicated for the treatment of spinal muscular atrophy (SMA). It is covered by South Dakota Medicaid following prior authorization when the following criteria are met:

** All requests under this policy require SD medical director review **in addition** to meeting specified criteria below **

- **Initial Therapy (must meet all):**
  - Therapy is prescribed by a board-certified pediatric neurologist with expertise in the treatment of SMA
  - Individual has an SMA diagnosis with submitted documentation (e.g., chart notes, laboratory values) confirming the mutation or deletion of genes in chromosome 5q resulting in homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13)
  - Individual has ≤3 copies of the SMN2 gene
  - Individual is ≥2 to <18 years of age
  - For use in a neonatal patient born prematurely, the full-term gestational age has been reached
  - Individual can sit independently but cannot stand or walk independently and does not have complete paralysis of limbs
  - Individual does not have severe contractures or scoliosis that would interfere with ability to receive intrathecal dosing
  - Individual is not dependent on **either** of the following:
    - Invasive ventilation or tracheostomy
    - Use of non-invasive ventilation beyond use for naps and nighttime sleep
  - Individual is not unable to receive nutrition through normal means (i.e. reliant on a gastric feeding tube for the majority of feedings)
  - Individual is not to receive routine concomitant SMN modifying therapy [e.g., Spinraza (nusinersen), Evrysdi (risdiplam)]. Patient's medical record will be reviewed and any current authorizations for SMN modifying therapy will be terminated upon Itvisma approval; patient access to subsequent SMN modifying therapy will be assessed according to respective coverage policy of concomitant agent
  - Individual does not have an elevated anti-adeno-associated virus serotype 9 (anti-AAV9) antibody titer above 1:50
  - Screening has been done within the last 6 months and documentation is provided indicating that the individual is negative for the following active diseases: HIV, Hepatitis B, and Hepatitis C
  - Individual does not have clinically significant abnormal laboratory values (defined as gamma-glutamyl transferase, ALT, AST or total bilirubin >2x upper limit of normal, creatinine ≥1.0mg/dL, hemoglobin <8 or >18 g/dL, WBC >20,000 per cmm)
  - Baseline functional status is documented by **one** of the following:
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder score (CHOP INTEND)
    - Hammersmith Infant Neurological Exam (HINE)
    - Hammersmith Functional Motor Scale Expanded (HFMSE)
  - If female, documentation of negative pregnancy test must be submitted prior to therapy
  - Male and female members of reproductive potential must use an effective method of contraception at start of treatment and at least 6 months following Itvisma administration
  - Individual has never received Itvisma or Zolgensma treatment in their lifetime
  - Approval duration: one dose
- **Continuation of Therapy:** not authorized

Itvisma is not covered for:

- The treatment of patients who have more than 3 copies of the SMN2 gene
- The treatment of SMA in patients younger than 2 years of age
- SMA without chromosome 5q mutations or deletions
- The routine combination treatment of SMA with concomitant SMN modifying therapy