



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 06/11/2026

Isembyld™ (apitegromab-mstn)

HCPCS: J3590

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved indication
 - b. FDA approved age
 - c. Prescribed by or in consultation with a neurologist specializing in pediatric neuromuscular disorders
 - d. Diagnosed with later-onset SMA (i.e., Type 2 and Type 3 SMA) before receiving an approved SMN-targeted therapy (i.e., either nusinersen or risdiplam)
 - e. Member is currently taking and anticipated to remain on background SMN-targeted therapy (i.e., either nusinersen or risdiplam)
 - f. Patient is not requiring invasive ventilation or tracheostomy
 - g. Patient has not had gene therapy treatment for SMA (such as Zolgensma)
 - h. Submission of a baseline, age appropriate exam to establish baseline motor function and ability. Examples of baseline motor ability assessments include:
 - i. Hammersmith Infant Neurological Exam (HINE)
 - ii. Hammersmith Functional Motor Scale Expanded (HFMSE)
 - iii. Upper Limb Module (ULM) Test (non-ambulatory patients)
 - iv. Six-Minute Walk Test (6MWT) (ambulatory patients only)
 - v. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
 - i. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by BCBSM
 - j. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list and/or BCBSM/BCN's prior authorization and step therapy documents
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limit: Align with FDA recommended dosing
 - b. Authorization Period: 6 months at a time
 - c. Renewal Criteria: Continuation of coverage requires submission of repeat motor ability assessment and documentation of response to therapy defined as a clinically significant improvement in SMA-associated motor milestones and motor function (for example, progression, stabilization, or decreased functional motor decline) compared to predicted natural history and progression.

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- SMA is a severe, inherited progressive neuromuscular disease that causes devastating muscle atrophy and disease-related complications in approximately 4 to 10 per 100,000 live births. SMA is caused by a mutation in the survival motor neuron 1 (SMN1) gene that results in a deficiency of SMN protein. People have a “backup” copy of this gene called SMN2 that produces low levels of SMN protein. SMA varies in severity with four different types that inversely correlates to the number of SMN2 copies a person has. The type of SMA a person has is based on the function and age of onset. Type 1 is the most severe type of SMA and the most commonly occurring. It affects 6 out of every 10 children with SMA. Those with Type 1 have the fewest number of SMN2 copies (usually 2 or fewer). Type 1 patients have an age of onset usually between 0-6 months, and as the natural history of those with Type 1 SMA progresses the children will never be able to sit unsupported. The life expectancy of untreated Type 1 patients is less than 2 years old. Type 2 patients usually present around 7-18 months of age and will have the ability to sit but never stand. The majority of SMA Type 2 patients have 3 copies of SMN2. Type 3 SMA patients present after 18 months of age and usually are able to stand and walk. About 51% of the patients with SMA Type 3 have 3 copies of SMN2 while 46% have 4 copies of SMN2. Although there is an inverse correlation between severity of disease and number of SMN2 copies, diagnoses of type is not solely based on number of SMN2 copies. Approximately 10,000 to 25,000 children and adults currently live with SMA in the US. It is estimated that around 30% of SMA cases are Type 2, and around 30% of SMA cases are Type 3.
- SMA guidelines found in Neuromuscular Disorders titled: Diagnosis and management of spinal muscular atrophy: Part 2: Pulmonary and acute care; medications, supplements and immunizations; other organ systems; and ethics have not been updated since 2018 and do not include recommendations for newer therapies. CureSMA has treatment recommendations and states that each individual or family must make treatment decisions based on needs, goals, and values in consultation and discussion with a healthcare provider. Timing is a key factor in SMA treatment and individuals with SMA should begin therapy as soon after diagnosis as possible. CureSMA describes the three available treatments of Spinraza, Zolgensma and Evrysdi and mentions that combination therapies between SMN-based and non-SMN treatments may provide the most benefit for those with SMA.

References:

1. Scholar Rock Investors and Media – Press Releases: Scholar Rock Submits Biologics License Application (BLA) to the U.S. FDA for Apatemab as a Treatment for Patients with Spinal Muscular Atrophy (SMA). January 29, 2025
<https://investors.scholarrock.com/news-releases/news-release-details/scholar-rock-submits-biologics-license-application-bla-us-fda>
2. Scholar Rock Investors and Media – Press Releases: Scholar Rock Reports Apatemab Meets Primary Endpoint in Phase 3 SAPPHIRE Study in Patients with Spinal Muscular Atrophy (SMA). October 7, 2024
<https://investors.scholarrock.com/news-releases/news-release-details/scholar-rock-reports-apatemab-meets-primary-endpoint-phase-3>
3. ClinicalTrials.gov Efficacy and Safety of Apatemab in Patients With Later-Onset Spinal Muscular Atrophy Treated With Nusinersen or Risdiplam (SAPPHIRE). ClinicalTrials.gov ID NCT05156320. Sponsor Scholar Rock, Inc. Information provided by Scholar Rock, Inc. (Responsible Party) Last Update Posted 2025-03-07
<https://clinicaltrials.gov/study/NCT05156320>
4. CureSMA – Spinal Muscular Atrophy Treatment. <https://www.curesma.org/spinal-muscular-atrophy-treatment/> accessed May 2025
5. Finkel RS, Chiriboga CA, Vajsar J, Day JW, Montes J, De Vivo DC, Yamashita M, Rigo F, Hung G, Schneider E, Norris DA, Xia S, Bennett CF, Bishop KM. Treatment of infantile-onset spinal muscular atrophy with nusinersen: a phase 2, open-label, dose-escalation study. Lancet. 2016 Dec 17; 388(10063):3017-3026.

Policy History												
#	Date	Change Description										
1.3	Effective Date: 10/01/2026	UM medical management system update for MAPPO and BCNA <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
BCN	Yes											
MAPPO	Yes											
BCNA	Yes											
1.2	Effective Date: 09/28/2026	UM medical management system update for BCBS and BCN <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
BCN	Yes											
MAPPO	No											
BCNA	No											
1.1	Effective Date: 06/11/2026	Annual review of criteria was performed, no changes were made										
1.0	Effective Date: 06/05/2025	Preliminary Drug Review <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	No											
BCN	No											
MAPPO	No											
BCNA	No											

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.*

Blue Cross Blue Shield/Blue Care Network of Michigan

Medication Authorization Request Form



This form is to be used by participating physicians to obtain coverage for **drugs covered under the medical benefit**. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	Name
ID Number	Specialty
D.O.B. ☐ Male ☐ Female	Address
Diagnosis	City /State/Zip
Drug Name	Phone/Fax: P: () - F: () -
Dose and Quantity	NPI
Directions	Contact Person
Date of Service(s)	Contact Person Phone / Ext.

STEP 1: DISEASE STATE INFORMATION

- Is this request for: ☐ Initiation ☐ Continuation Date patient started therapy: _____
- Administered by patient or a medical professional? ☐ patient (self) ☐ health care professional (physician, nurse, etc.)
- Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
☐ Hospital outpatient facility (go to #4) Reason for Hospital Outpatient administration: _____
☐ Hospital inpatient facility for Car-T therapy only (for example: Kymriah, Yescarta, or Tecartus) (go to #5)
- Please specify location of administration if hospital outpatient infusion: _____
- Please specify location of administration if hospital inpatient infusion: _____
- Please provide the NPI number for the place of administration: _____
- Initiation AND Continuation of therapy:**
 - What is the patient's diagnosis? _____
 - What other medication has the patient received for their condition? Please list _____
 - Please describe the response to previous therapies: _____
 - Will the patient be receiving any other treatment for the listed condition while on this medication? Please list: _____
 - Please list any labs values important for diagnosing or monitoring this patient's condition: _____
- Continuation of therapy:**
 - Has the patient progressed while on this medication? ☐ yes ☐ no
 - How has the patient's condition changed while on this medication?

☐ Improved: Please describe: _____
 ☐ Stable: please describe: _____
 ☐ Worsened; Please describe: _____
 ☐ Other; Please describe: _____

Chart notes are required for the processing of all requests. Please add any other supporting medical information necessary for our review (required)

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name	Physician Signature	Date
Step 2: Checklist	☐ Form Completely Filled Out ☐ Provide chart notes	☐ Attach test results
Step 3: Submit	By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979	By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320

Confidentiality notice: This transmission contains confidential information belonging to the sender that is legally privileged. This information is intended only for use of the individual or entity named above. The authorized recipient of this information is prohibited from disclosing this information to any other party. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or action taken in reliance on the contents of this document is strictly prohibited. If you have received this in error, please notify the sender to arrange for the return of this document.

7/26/2018, 9/18/2018; 1/31/2020; 3/17/2020; 8/9/2021