

Preemptive policy: This is a P&T approved policy and can be used after the drug is FDA approved until it is superseded by an updated policy



Clinical Policy: Apitegromab (SRK-015)

Reference Number: CP.PHAR.737

Effective Date: **FDA Approval Date**

Last Review Date: 08.25

Line of Business: Commercial, HIM, Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Apitegromab (SRK-015^{®/TM}) is an anti-promyostatin monoclonal antibody.

FDA Approved Indication(s) [Pending]

SRK-015 is indicated for the treatment of motor function improvement for patients with spinal muscular atrophy (SMA) who are concurrently being treated with nusinersen or risdiplam.

Limitation(s) of use: [XXX]

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that SRK-015 is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. Spinal Muscular Atrophy (must meet all):

1. Diagnosis of SMA confirmed by the presence of one of the following (a, b, or c):*
 - a. Homozygous deletions of SMN1 gene (e.g., absence of the SMN1 gene);
 - b. Homozygous mutation in the SMN1 gene (e.g., biallelic mutations 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));
2. Documentation of genetic testing confirming no more than 4 copies of SMN2 gene;*
3. Prescribed by or in consultation with a neurologist;
4. Age \geq 2 years;*
5. Member meets one of the following (a or b):*
 - a. Has been receiving Spinraza[®] for at least 10 months;
 - b. Has been receiving Evrysdi[®] for at least 6 months;
6. Member is concurrently receiving treatment with Spinraza or Evrysdi;*
7. Member has not been previously treated with Zolgensma[®];*
8. Documentation of baseline Hammersmith functional motor scale expanded (HFMSE) score;

9. Member does not require tracheostomy or invasive or noninvasive ventilation for > 16 hours/day continuously for \geq 14 days;*
10. Documentation of member's current weight in kg;*
11. Dose does not exceed 20 mg/kg every 4 weeks.*

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. Spinal Muscular Atrophy (must meet all):

1. Currently receiving medication for SMA with 1 to 4 copies of the SMN2 gene, or member has previously met initial approval criteria;*
2. Member does not require tracheostomy or invasive or noninvasive ventilation for > 16 hours/day continuously for \geq 14 days;*
3. Member is responding positively to therapy as evidenced by one of the following (a or b):*
 - a. Must demonstrate HFMSE score improvement or maintenance of previous score improvement from baseline;
 - b. Member has not had a decline in motor function test score(s) from baseline AND medical justification demonstrates and supports that member is responding positively to therapy;
4. Member is concurrently receiving treatment with Spinraza or Evrysdi;*
5. Member has not been previously treated with Zolgensma;*
6. Documentation of member's current weight in kg;*
7. If request is for a dose increase, new dose does not exceed 20 mg/kg every 4 weeks.*

Approval duration:

Medicaid/HIM – 12 months

Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

HFMSE: Hammersmith functional

motor scale expanded

SMA: spinal muscular atrophy

SMN: survival motor neuron

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Evrysdi [®] (risdiplam)	Weight-based dose PO QD: <ul style="list-style-type: none"> • Less than 2 months of age: 0.15 mg/kg • 2 months to less than 2 years of age: 0.2 mg/kg • 2 years of age and older, weighing less than 20 kg: 0.25 mg/kg • 2 years of age and older, weighing 20 kg or more: 5 mg 	5 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Spinraza [®] (nusinersen)	<p>Initial (4 loading doses): 12 mg intrathecally every 14 days for 3 doses (loading doses); then, a fourth loading dose of 12 mg intrathecally 30 days after the third loading dose</p> <p>Maintenance: 12 mg intrathecally every 4 months</p>	12 mg intrathecally every 4 months

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings [Pending]

- Contraindication(s): **pending**
- Boxed warning(s): **pending**

Appendix D: General Information

- SMA is an autosomal recessive genetic disorder. It is caused by mutations in the SMN1 (survival motor neuron) gene that is found on chromosome 5 (hence the name 5q-SMA). To develop SMA, an individual must inherit two faulty (deletion or mutation) SMN1 genes, one from each parent.
- SMN-related SMA is classified as type 1 through 4 depending on time of onset. The age of disease onset of symptoms correlates with disease severity: the earlier the age of onset, the greater the impact on motor function. Children who display symptoms at birth or in infancy typically have the lowest level of functioning (type 1). SMA onset in children (types 2 and 3), teens or adults (type 4) generally correlates with increasingly higher levels of motor function.
- SMN2 gene copy and SMA types
 - SMN2 gene copy numbers are variable in individuals with spinal muscular atrophy. Higher numbers typically correlate with less severe disease.
 - More than 95% of individuals with spinal muscular atrophy retain at least 1 copy of the SMN2 gene
 - About 80% of individuals with Type I spinal muscular atrophy have 1 or 2 copies of the SMN2 gene
 - About 82% of individuals with Type II spinal muscular atrophy have 3 copies of the SMN2 gene
 - About 96% of individuals with Type III spinal muscular atrophy have 3 or 4 copies of the SMN2 gene
- The HFSME score combines the Hammersmith Functional Motor Scale with a 13-item expansion module for ability to distinguish motor skills among individuals who may be older or with SMA types II and III. Each item is graded from 0 to 3, with 0 signifying no response, with a total of 66 points. HFMSE has demonstrated reliability and validity in patients with SMA. An increase of greater than 2 points in total score is unlikely in untreated SMA.

V. Dosage and Administration [Pending]

Indication	Dosing Regimen	Maximum Dose
SMA*	10 mg/kg to 20 mg/kg IV every 4 weeks*	20 mg/kg IV every 4 weeks*

VI. Product Availability [Pending]

Pending

VII. References

1. ClinicalTrials.gov. Efficacy and safety of apitegromab in patients with later-onset spinal muscular atrophy treated with nusinersen or risdiplam. Available at: <https://clinicaltrials.gov/study/NCT05156320>. Accessed March 19, 2025.
2. Mercuri E, Finkel RS, Muntoni F, et al. Diagnosis and management of spinal muscular atrophy: Part 1: Recommendations for diagnosis, rehabilitation, orthopedic and nutritional care. *Neuromuscul Disord*. 2018;28(2):103-115.
3. Finkel RS, Mercuri E, Meyer OH, et al. Diagnosis and management of spinal muscular atrophy: Part 2: Pulmonary and acute care; medications, supplements, and immunizations; other organ systems; and ethics. *Neuromuscul Disord*. 2018;28(3):197-207.
4. Schroth M, Deans J, Arya K, et al. Spinal muscular atrophy update in best practices: recommendations for diagnosis considerations. *Neurol Clin Pract*. 2024 Aug;14(4):e200310. doi: 10.1212/CPJ.0000000000200310.
5. Crawford TO, Day JW, De Vivo DC, et al. Long-term efficacy, safety, and patient-reported outcomes of apitegromab in patients with spinal muscular atrophy: results from the 36-month TOPAZ study. *Front Neurol*. 2024 Jul 22;15:1419791. doi: 10.3389/fneur.2024.1419791. PMID: 39105058; PMCID: PMC11299114.

Coding Implications [Pending]

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
Pending	Pending

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	06.03.25	08.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and

accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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