

Clinical Policy: Eltrombopag (Alvaiz, Promacta)

Reference Number: CP.PHAR.180

Effective Date: 03.01.16

Last Review Date: 02.25

Line of Business: Commercial, HIM*, Medicaid

[Revision Log](#)

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

Description

Eltrombopag (Alvaiz[™], Promacta[®]) is a thrombopoietin receptor agonist.

**For Health Insurance Marketplace (HIM), if request is through pharmacy benefit, Alvaiz is non-formulary and should not be approved using these criteria; refer to the formulary exception policy, HIM.PA.103.*

FDA Approved Indication(s)

Promacta is indicated for the treatment of:

- Thrombocytopenia in adult and pediatric patients 1 year and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Promacta should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.
- Thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. Promacta should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy.
- In combination with standard immunosuppressive therapy for the first-line treatment of adults and pediatric patients 2 years and older with severe aplastic anemia.
- Patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

Alvaiz is indicated for the treatment of:

- Thrombocytopenia in adult and pediatric patients 6 years and older with persistent or chronic ITP who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Alvaiz should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.
- Thrombocytopenia in adult patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. Alvaiz should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy.
- Adult patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

Limitation(s) of use:

- Promacta and Alvaiz are not indicated for the treatment of patients with myelodysplastic syndromes (MDS).

- Safety and efficacy of Promacta and Alvaiz have not been established in combination with direct-acting antiviral agents used without interferon for treatment of chronic hepatitis C infection.

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 Alvaiz and Promacta are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Persistent/Chronic Immune Thrombocytopenia (must meet all):

1. Diagnosis of persistent or chronic ITP (*see Appendix D*);
2. Prescribed by or in consultation with a hematologist;
3. Age is one of the following (a or b):
 - a. For Promacta: ≥ 1 year;
 - b. For Alvaiz: ≥ 6 years;
4. One of the following (a or b):
 - a. Current (within 30 days) platelet count is $< 30,000/\mu\text{L}$;
 - b. Member has an active bleed;
5. Member meets one of the following (a or b):
 - a. Failure of a systemic corticosteroid;
 - b. Member has intolerance or contraindication to systemic corticosteroids, and failure of an immune globulin, unless contraindicated or clinically significant adverse effects are experienced (*see Appendix B*);

**Prior authorization may be required for immune globulins*
6. Promacta and Alvaiz are not prescribed concurrently with rituximab, another thrombopoietin receptor agonist (e.g., Doptelet[®], Mulpleta[®], Nplate[®]), or spleen tyrosine kinase inhibitor (e.g., Tavalisse[™]);
7. Dose does not exceed 1 tablet per day and one of the following (a or b):
 - a. For Promacta: 75 mg per day;
 - b. For Alvaiz: 54 mg per day.

Approval duration: 6 months

B. Chronic Hepatitis C-Associated Thrombocytopenia (must meet all):

1. Diagnosis of chronic hepatitis C-associated thrombocytopenia;
2. Prescribed by or in consultation with a hematologist, hepatologist, gastroenterologist or infectious disease specialist;
3. Age ≥ 18 years;
4. Promacta or Alvaiz will be used concomitantly with interferon-based therapy;
5. The degree of thrombocytopenia has prevented the initiation of interferon-based therapy or limited the ability to maintain interferon-based therapy;
6. Current (within 30 days) platelet count is $< 75,000/\mu\text{L}$;

7. Promacta and Alvaiz are not prescribed concurrently with another thrombopoietin receptor agonist (e.g., Doptelet, Mulpleta, Nplate) or spleen tyrosine kinase inhibitor (e.g., Tavalisse);
8. Dose does not exceed 2 tablets per day and one of the following (a or b):
 - a. For Promacta: 100 mg per day;
 - b. For Alvaiz: 72 mg per day.

Approval duration: 6 months

C. Severe Aplastic Anemia (must meet all):

1. Diagnosis of severe aplastic anemia;
2. Prescribed by or in consultation with a hematologist;
3. Age is one of the following (a or b):
 - a. For Promacta: ≥ 2 years;
 - b. For Alvaiz: ≥ 18 years;
4. Prescribed for one of the following (a or b):
 - a. For Promacta only: As first-line therapy in combination with immunosuppressive therapy (e.g., Atgam[®], cyclosporine, cyclophosphamide);
 - b. Refractory or second-line treatment as a single agent following insufficient response to immunosuppressive therapy (e.g., Atgam, cyclosporine, cyclophosphamide);

**Prior authorization may be required for Atgam and cyclophosphamide*
5. Current (within 30 days) platelet count is $< 50,000/\mu\text{L}$;
6. Promacta and Alvaiz are not prescribed concurrently with another thrombopoietin receptor agonist (e.g., Doptelet, Mulpleta, Nplate) or spleen tyrosine kinase inhibitor (e.g., Tavalisse);
7. Dose does not exceed 2 tablets per day and one of the following (a or b):
 - a. For Promacta: 150 mg per day;
 - b. For Alvaiz: 108 mg per day.

Approval duration: 6 months

D. NCCN Compendium Indications (off-label) (must meet all):

1. Prescribed for one of the following (a or b):
 - a. MDS;
 - b. Post-hematopoietic cell transplant with prolonged thrombocytopenia;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. For MDS: Member has lower-risk MDS (IPSS-R [Very Low, Low, Intermediate]);
4. For MDS: Member has one of the following (a, b, c, or d):
 - a. Severe thrombocytopenia;
 - b. Refractory thrombocytopenia following disease progression or no response to hypomethylating agents (e.g., azacitadine, decitabine), immunosuppressive therapy (e.g., Atgam, cyclosporine), or clinical trial;
 - c. Thrombocytopenia or neutropenia and one of the following (i, ii, iii, or iv):
 - i. Age ≤ 60 years with $\leq 5\%$ marrow blasts;
 - ii. Hypocellular marrows;
 - iii. Paroxysmal nocturnal hemoglobinuria (PNH) clone positivity;
 - iv. *STAT-3* mutant cytotoxic T-cell clones;

- d. Symptomatic anemia with good probability to respond to immunosuppressive therapy;
5. Promacta and Alvaiz are not prescribed concurrently with another thrombopoietin receptor agonist (e.g., Doptelet, Mulpleta, Nplate);
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

E. 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

A. Persistent/Chronic Immune Thrombocytopenia, Chronic Hepatitis C-Associated Thrombocytopenia and Severe Aplastic Anemia (must meet all):

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy (*see Appendix D*);
3. Current (within the last 90 days) platelet count is $< 400,000/\mu\text{L}$;
4. For chronic hepatitis C-associated thrombocytopenia, member continues to receive interferon-based therapy;
5. Promacta and Alvaiz are not prescribed concurrently with another thrombopoietin receptor agonist (e.g., Doptelet, Mulpleta, Nplate) or spleen tyrosine kinase inhibitor (e.g., Tavalisse);
6. For persistent or chronic ITP: Promacta and Alvaiz are not prescribed concurrently with rituximab;

7. If request is for a dose increase, new dose does not exceed the following:
 - a. For persistent or chronic ITP: 1 tablet per day and either (i or ii):
 - i. For Promacta: 75 mg per day;
 - ii. For Alvaiz: 54 mg per day;
 - b. For chronic hepatitis C-associated thrombocytopenia: 2 tablets per day and either (i or ii):
 - i. For Promacta: 100 mg per day;
 - ii. For Alvaiz: 72 mg per day;
 - c. For severe aplastic anemia: 2 tablets per day and either (i or ii):
 - i. For Promacta: 150 mg per day;
 - ii. For Alvaiz: 108 mg per day.

Approval duration:

Hepatitis C-associated thrombocytopenia – 6 months;

All other indications – 12 months

B. NCCN Compendium Indications (off-label) (must meet all):

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Promacta or Alvaiz for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Promacta and Alvaiz are not prescribed concurrently with another thrombopoietin receptor agonist (e.g., Doptelet, Mulpleta, Nplate);
4. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

C. 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

ANC: absolute neutrophil count

FDA: Food and Drug Administration

IPSS-R: Revised International

Prognostic Scoring System

ITP: chronic immune thrombocytopenia

MDS: myelodysplastic syndromes

PNH: paroxysmal nocturnal

hemoglobinuria

STAT-3: signal transducer and activator of transcription

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
Corticosteroids*		
dexamethasone	ITP <u>Oral dosage:</u> <i>Adults:</i> Initially, 0.75 to 9 mg/day PO, given in 2 to 4 divided doses. Adjust according to patient response. <i>Children and adolescents:</i> 0.02 to 0.3 mg/kg/day PO or 0.6 to 9 mg/m²/day PO, given in 3 to 4 divided doses <u>Intramuscular or intravenous dosage:</u> <i>Adults:</i> Initially, 0.5 to 9 mg/day IV or IM, given in 2 to 4 divided doses. Adjust according to patient response. <i>Children:</i> 0.02 to 0.3 mg/kg/day or 0.6 to 9 mg/m²/day IV or IM given in 3-4 divided doses. Adjust according to patient response.	Dosage must be individualized and is highly variable depending on the nature and severity of the disease, route of treatment, and on patient response.
methylprednisolone	ITP <u>Oral dosage:</u> <i>Adults:</i> 4 to 48 mg/day PO in 4 divided doses. Adjust according to patient response. <i>Children:</i> 0.5 to 1.7 mg/kg/day PO in divided doses every 6 to 12 hrs <u>Intravenous dosage:</u>	Dosage must be individualized and is highly variable depending on the nature and severity of the disease, route of treatment, and on patient response.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<i>Adults:</i> 10 to 40 mg IV every 4 to 6 hours for up to 72 hours <i>Children:</i> 0.11 to 1.6 mg/kg/day IV in 3 or 4 divided doses.	
prednisone	ITP <i>Adults:</i> Initially, 1 mg/kg PO once daily; however, lower doses of 5 mg/day to 10 mg/day PO are preferable for long-term treatment.	Dosage must be individualized and is highly variable depending on the nature and severity of the disease, route of treatment, and on patient response.
Immune globulins		
immune globulins (e.g., Flebogamma [®] DIF 10%, Gammagard [®] S/D, Gammaked [™] , Gamunex [®] -C, Gammaplex [®] , Octagam [®] 10%, Privigen [®])	ITP Refer to prescribing information	Refer to prescribing information
Immunosuppressive agents*		
Atgam [®] (antithymocyte globulin)	Aplastic anemia 10 to 20 mg/kg/day IV infusion for 8 to 14 days, continuing with every-other-day dosing up to a total of 21 doses, if needed Off-label dosing: 40 mg/kg IV daily for four consecutive days in combination with cyclosporine	Varies
cyclosporine [†] (Sandimmune [®])	Aplastic anemia 12 mg/kg PO daily	Varies
cyclophosphamide [†]	Aplastic anemia 45 to 50 mg/kg IV divided over 4 days	Varies

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.

*Examples of corticosteroids/immunosuppressive agents provided are not all inclusive

[†]Off-label indication

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported

- Boxed warning(s): risk for hepatic decompensation in patients with chronic hepatitis C and risk of hepatotoxicity

Appendix D: General Information

- Definition of persistent vs chronic ITP per the 2019 American Society of Hematology Guideline
 - Persistent ITP: ITP duration of 3-12 months
 - Chronic ITP: ITP duration of > 12 months
- Examples of positive response to therapy may include:
 - For ITP or hepatitis C-associated thrombocytopenia:
 - Increase in platelet count from baseline levels;
 - Platelet count $\geq 50,000/\mu\text{L}$;
 - Reduction in clinically important bleeding events;
 - For aplastic anemia: any of the following hematologic responses:
 - Platelet count $\geq 50,000/\mu\text{L}$
 - Platelet count increases to $20,000/\mu\text{L}$ above baseline or stable platelet counts with transfusion independence for a minimum of 8 weeks;
 - Hemoglobin increase $> 1.5 \text{ g/dL}$, or a reduction of ≥ 4 units of red blood cell (RBC) transfusions for 8 consecutive weeks;
 - Absolute neutrophil count (ANC) increase of 100% or an ANC increase greater than $500/\mu\text{L}$.
- MDS prognostic scoring system online calculator for IPSS-R:
https://qxmd.com/calculate/calculator_109/mds-revised-international-prognostic-scoring-system-ipss-r

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Eltrombopag (Promacta)	Persistent or chronic ITP	Adults and pediatrics age ≥ 6 years: 50 mg PO QD Pediatrics age 1 to 5 years: 25 mg PO QD Adjust to maintain platelet count $\geq 50,000/\mu\text{L}$.	75 mg/day
	Chronic hepatitis C-associated thrombocytopenia	25 mg PO QD Adjust to achieve target platelet count required to initiate antiviral therapy.	100 mg/day
	Severe aplastic anemia	<u>After an insufficient response to immunosuppressive therapy:</u> 50 mg PO QD Adjust to maintain platelet count $\geq 50,000/\mu\text{L}$.	150 mg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
		<u>For first-line treatment in combination with immunosuppressive therapy:</u> Patients ≥ 12 years: 150 mg PO QD Patients 6 to 11 years: 75 mg PO QD Patients 2 to 5 years: 2.5 mg/kg PO QD Adjust to maintain platelet count $\geq 50,000/\mu\text{L}$. Total duration of treatment is 6 months.	
Eltrombopag (Alvaiz)	Persistent or chronic ITP	Adults and pediatrics age ≥ 6 years: 36 mg PO QD Adjust to maintain platelet count $\geq 50,000/\mu\text{L}$.	54 mg/day
	Chronic hepatitis C-associated thrombocytopenia	18 mg PO QD Adjust to achieve target platelet count required to initiate antiviral therapy.	72 mg/day
	Severe aplastic anemia	<u>After an insufficient response to immunosuppressive therapy:</u> 36 mg PO QD Adjust to maintain platelet count $\geq 50,000/\mu\text{L}$.	108 mg/day

VI. Product Availability

Drug Name	Availability
Eltrombopag (Promacta)	Oral tablets: 12.5 mg, 25 mg, 50 mg, 75 mg Oral suspension: 12.5 mg, 25 mg
Eltrombopag (Alvaiz)	Oral tablets: 9 mg, 18 mg, 36 mg, 54 mg

VII. References

1. Alvaiz Prescribing Information. Parsippany, NJ: Teva; July 2024. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ed51e463-7a03-4858-bbd2-882ce4753d5a>. Accessed November 20, 2024.
2. Promacta Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2023. Available at: https://www.novartis.com/us-en/sites/novartis_us/files/promacta.pdf. Accessed November 20, 2024.
3. Townsley DM, et al. Eltrombopag added to standard immunosuppression for aplastic anemia. N Engl J of Med. Apr 2017;376(16):1540-1550.
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Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2021 annual review: for aplastic anemia clarified use either as first-line combination therapy or second-line as monotherapy, removed upper age limit for combination therapy per clinical trial baseline characteristics of study population; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	11.17.20	02.21
RT4: updated criteria in response to FDA label revision to include persistent or chronic ITP	02.23.21	
1Q 2022 annual review: clarified definition of persistent vs chronic ITP in Appendix D per 2019 ASH guideline; for MDS removed IPSS and WPSS risk categorizations as IPSS-R is preferred per NCCN; included criteria for specific circumstances for MDS where disease progression on other agents is not necessary per NCCN; references reviewed and updated.	11.15.21	02.22
Template changes applied to other diagnoses/indications.	10.03.22	
1Q 2023 annual review: per NCCN Compendium, for MDS added off-label indication of symptomatic anemia and its qualifiers; references reviewed and updated.	10.31.22	02.23
1Q 2024 annual review: added NCCN Compendium-supported indication of prolonged thrombocytopenia post-hematopoietic cell transplant; added exclusion of concurrent thrombopoietin receptor agonist with Promacta to aplastic anemia, chronic hepatitis C-associated thrombocytopenia, and NCCN Compendium indications; for all FDA-labeled indications added exclusion of concurrent spleen tyrosine kinase inhibitor (e.g., Tavalisse™); references reviewed and updated. RT4: added Alvaiz, a new eltrombopag choline formulation.	01.08.24	02.24
1Q 2025 annual review: added disclaimer that for HIM line of business Alvaiz is non-formulary; per NCCN Compendium, for MDS removed that request must be for Promacta and for MDS with	11.20.24	02.25

Reviews, Revisions, and Approvals	Date	P&T Approval Date
symptomatic anemia removed requirement for no del(5q) and serum erythropoietin; references reviewed and updated.		

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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