PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Thrombocytopenia – Eltrombopag Products Preferred Specialty Management Policy
- Alvaiz™ (eltrombopag choline tablets – Teva)
- Promacta® (eltrombopag olamine tablets and oral suspension – Novartis)

REVIEW DATE: 05/15/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Promacta and Alvaiz are thrombopoietin receptor agonists.[1,2] Alvaiz is FDA-approved for the treatment of thrombocytopenia in adult and pediatric patients ≥ 6 years of age with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy; thrombocytopenia in adults with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy; and severe aplastic anemia in adults who have had an insufficient response to immunosuppressive therapy.[2] FDA-approved uses for Promacta overlap with Alvaiz.[1] However, Promacta has slightly more expansive indications. For example, the chronic ITP indication for Promacta has a lower age threshold (≥ 1 year of age). Also, Promacta has an additional indication for use in combination with standard immunosuppressive therapy for the first-line treatment of adult and pediatric patients ≥ 2 years of age with severe aplastic anemia. Alvaiz is the choline salt of eltrombopag and the tablets are available in the following strengths: 9 mg, 18 mg, 36 mg, and 54 mg. Promacta is the olamine salt and the tablets are available in the following strengths: 12.5 mg, 25 mg, 50

mg, and 75 mg. Promacta is also available as an oral suspension (12.5 mg and 25 mg packets).

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Products. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The program also directs the patient to try one Preferred Product prior to the approval of a Non-Preferred Product. If the patient meets the standard *Thrombocytopenia – Eltrombopag Products Prior Authorization Policy* criteria but has not tried a Preferred Product, approval for a Preferred Product will be authorized. Approval durations are as noted in the respective standard *Thrombocytopenia – Eltrombopag Products Prior Authorization Policy*. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below).

Documentation: Documentation is required for use of Promacta as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information.

Preferred Products: Promacta tablets and oral suspension
Non-Preferred Products: Alvaiz

Thrombocytopenia – Eltrombopag Products non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Alvaiz	**1.** Approve for the duration noted in the standard *Thrombocytopenia – Eltrombopag Products Prior Authorization Policy* if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Thrombocytopenia – Eltrombopag Products Prior Authorization Policy* criteria; AND **B)** Patient meets ONE of the following (i or ii): **i.** Patient has tried Promacta **[documentation required]**; OR **ii.** Patient is currently receiving Alvaiz; OR **2.** If the patient has met the standard *Thrombocytopenia – Eltrombopag Products Prior Authorization Policy* criteria (1A),but has not met exception criteria (1B): approve Promacta.

REFERENCES

1. Promacta® tablets and oral suspension [prescribing information]. East Hanover, NJ: Novartis; March 2023.
2. Alvaiz™ tablets [prescribing information]. Parsippany, NJ: Teva; November 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	05/15/2024