AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Promacta	Page:	1 of 7
Effective Date:	5/25/2023	Last Review Date:	3/1/2023

Applies to:	☒Illinois ☒Maryland ☒Michigan	☐Florida ☒Florida Kids ☒ Virginia	☒New Jersey ☒Pennsylvania Kids

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Promacta under the patient's prescription drug benefit.

Description:

A. FDA-Approved Indications
- 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
- Treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy
- First-line treatment of severe aplastic anemia in adult and pediatric patients 2 years and older in combination with standard immunosuppressive therapy
- Treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy

B. Compendial Uses
- MYH9-related disease with thrombocytopenia
- Myelodysplastic syndromes, for lower risk disease in patients with severe or refractory thrombocytopenia following disease progression or no response to hypomethylating agents, immunosuppressive therapy, or clinical trial.
- Myelodysplastic syndromes, in combination with equine anti-thymocyte globulin with or without cyclosporine, for treatment of lower risk disease in select patients (generally ≤60 years old and with ≤5% marrow blasts, or those with hypocellular marrows, PNH clone positivity, or STAT-3 mutant cytotoxic T-cell clones) with clinically relevant thrombocytopenia or neutropenia.

C. All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Promacta

Policy/Guideline:

Criteria for Initial Approval:

I. Authorization may be granted for chronic or persistent immune thrombocytopenia when the following criteria are met:

- There was an inadequate response or intolerance to prior therapy with corticosteroids, immunoglobulins, or splenectomy
- Documentation of untransfused platelet count at any point prior to the initiation of the requested medication is less than 30x109/L OR 30x109/L to 50x109/L with symptomatic bleeding (e.g., significant mucous membrane bleeding, gastrointestinal bleeding, or trauma) or risk factors for bleeding
    - Examples of risk factors for bleeding (not all inclusive):
        - Undergoing a medical or dental procedure where blood loss is anticipated
        - Comorbidity (e.g., peptic ulcer disease, hypertension)
        - Mandated anticoagulation therapy
        - Profession (e.g., construction worker) or lifestyle (e.g., plays contact sports) that predisposes member to trauma
- Medication is prescribed by or is in consultation with a hematologist or oncologist
- Promacta is not used concomitantly with other thrombopoietin receptor agonists (e.g., Nplate, Doptelet, Mulpleta) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse)

II. Authorization may be granted for thrombocytopenia associated with chronic hepatitis C when the following criteria are met:

- Request is for the initiation and maintenance of interferon-based therapy for the treatment of thrombocytopenia associated with chronic hepatitis C
- Medication is prescribed by or is in consultation with a hematologist or oncologist
- Promacta is not used concomitantly with other thrombopoietin receptor agonists (e.g., Nplate, Doptelet, Mulpleta) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse)

III. Authorization may be granted for aplastic anemia when the following criteria are met:

- Request is for first-line treatment of severe aplastic anemia when Promacta will be used in combination with standard immunosuppressive therapy (e.g., horse antithymocyte globulin (h-ATG) and cyclosporine).
- Request is for treatment of aplastic anemia which had an insufficient response to immunosuppressive therapy
- Medication is prescribed by or is in consultation with a hematologist or oncologist

- Promacta is not used concomitantly with other thrombopoietin receptor agonists (e.g., Nplate, Doptelet, Mulpleta) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse)

IV. Authorization may be granted for MYH9-related disease with thrombocytopenia when the following criteria are met:

- Request is for thrombocytopenia associated with MYH9-related disease
- Medication is prescribed by or is in consultation with a hematologist or oncologist
- Promacta is not used concomitantly with other thrombopoietin receptor agonists (e.g., Nplate, Doptelet, Mulpleta) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse)

V. Authorization may be granted for myelodysplastic syndromes when the following criteria are met:

- Treatment is for myelodysplastic syndromes with severe or refractory thrombocytopenia:
  - Member has lower risk disease defined as Revised International Prognostic Scoring System (IPSS-R) (Very Low, Low, Intermediate), International Prognostic Scoring System (IPSS) (Low/Intermediate-1), WHO classification-based Prognostic Scoring System (WPSS) (Very Low, Low, Intermediate).
  - Member has severe or refractory thrombocytopenia following disease progression or no response to hypomethylating agents (such as azacitidine and decitabine), immunosuppressive therapy, or clinical trial.
  - Medication is prescribed by or is in consultation with a hematologist or oncologist
  - Promacta is not used concomitantly with other thrombopoietin receptor agonists (e.g., Nplate, Doptelet, Mulpleta) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse)
- Treatment is for myelodysplastic syndromes:
  - Member has lower risk disease defined as Revised International Prognostic Scoring System (IPSS-R) (Very Low, Low, Intermediate), International Prognostic Scoring System (IPSS) (Low/Intermediate-1), WHO classification-based Prognostic Scoring System (WPSS) (Very Low, Low, Intermediate).
  - Member has clinically relevant thrombocytopenia or neutropenia.
  - Promacta will be used in combination with equine anti-thymocyte globulin.

- Medication is prescribed by or is in consultation with a hematologist or oncologist
- Promacta is not used concomitantly with other thrombopoietin receptor agonists (e.g., Nplate, Doptelet, Mulpleta) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse)

Criteria for Continuation of Therapy

I. Authorization may be granted for chronic or persistent immune thrombocytopenia when the following criteria are met:

- Medication is prescribed by or is in consultation with a hematologist or oncologist
- Promacta is not used concomitantly with other thrombopoietin receptor agonists (e.g., Nplate, Doptelet, Mulpleta) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse)
- Current platelet count is less than 50x109/L and the platelet count is not sufficient to prevent clinically important bleeding, as the maximal Promacta dose has not been received for at least 4 weeks
- Current platelet count is less than 50x109/L and the current platelet count is sufficient to prevent clinically important bleeding
- Current platelet count of 50x109/L to 200x109/L
- Current platelet count is greater than 200x109/L to less than or equal to 400x109/L, and dosing will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding

II. Authorization may be granted for thrombocytopenia associated with chronic hepatitis C when the following criteria are met:

- The member is continuing to receive interferon-based therapy
- Medication is prescribed by or is in consultation with a hematologist or oncologist
- Promacta is not used concomitantly with other thrombopoietin receptor agonists (e.g., Nplate, Doptelet, Mulpleta) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse)

III. Authorization may be granted for aplastic anemia when the following criteria are met:

- Member has a current platelet count less than 50x109/L and has not received the appropriately titrated therapy with Promacta for at least 16 weeks
- Member has a current platelet count less than 50x109/L and is transfusion independent

- Member has a current platelet count 50x109/L to 200x109/L
- Member has a current platelet count greater than 200 x109/L to less than or equal to 400x109/L and for whom Promacta dosing will be adjusted to achieve and maintain an appropriate target platelet count
- Medication is prescribed by or is in consultation with a hematologist or oncologist
- Promacta is not used concomitantly with other thrombopoietin receptor agonists (e.g., Nplate, Doptelet, Mulpleta) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse)

VI. Authorization may be granted for MYH9-related disease with thrombocytopenia when the following criteria are met:

- All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria

VII. Authorization may be granted for Myelodysplastic Syndromes when the following criteria are met:

- Member has experienced benefit from therapy (e.g., increased platelet counts, decreased bleeding events, reduced need for platelet transfusions)
- Medication is prescribed by or is in consultation with a hematologist or oncologist
- Promacta is not used concomitantly with other thrombopoietin receptor agonists (e.g., Nplate, Doptelet, Mulpleta) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse)

Approval Duration and Quantity Restrictions:

Initial Approval:

- 6 months
  - Chronic or persistent immune thrombocytopenia (ITP)
  - Thrombocytopenia associated with chronic hepatitis C
  - Aplastic anemia
- 12 months
  - MYH9-related disease with thrombocytopenia
  - Myelodysplastic Syndromes

Renewal Approval:

- Chronic or persistent ITP
  - 3 months

        - Current platelet count is <50x109/L and the platelet count is not sufficient to prevent clinically important bleeding in member who has not received the maximal Promacta dose for at least 4 weeks
    - 12 months
        - Current platelet count is <50x109/L and the current platelet count is sufficient to prevent clinically important bleeding
        - Current platelet count is 50x109/L to 200x109/L
        - Current platelet count is >200x109/L to ≤400x109/L and the Promacta dosing is to be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding
- Aplastic anemia
    - 16 weeks
        - Current platelet count is <50x109/L and member has not received appropriately titrated therapy with Promacta for at least 16 weeks
        - Current platelet count is <50x109/L and member is transfusion-independent
    - 12 months
        - Current platelet count is 50x109/L to 200x109/L
        - Current platelet count is >200 x109/L to ≤400x109/L and dosing is to be adjusted to achieve and maintain an appropriate target platelet count
- Thrombocytopenia associated with chronic hepatitis C
    - 6 months
- Myelodysplastic Syndromes
    - 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

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