Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 330.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Tremfya (guselkumab)

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Tremfya (guselkumab)

II. Purpose/Objective:
To provide a policy of coverage regarding Tremfya (guselkumab)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

DESCRIPTION:
Tremfya (guselkumab) is a human monoclonal IgG1λ antibody that selectively binds to the p19 subunit of interleukin 23 (IL-23) and inhibits its interaction with the IL-23 receptor. IL-23 is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Guselkumab inhibits the release of proinflammatory cytokines and chemokines.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Tremfya (guselkumab) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when all of the following criteria are met:

- Medical record documentation that Tremfya is prescribed by a gastroenterologist **AND**
- Medical record documentation of a diagnosis of moderately to severely active ulcerative colitis **AND**
- Medical record documentation that Tremfya is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one conventional systemic therapy* (e.g. corticosteroids, immunomodulators such as azathioprine, 6 mercaptopurine, cyclosporine, tacrolimus) **OR** medical record documentation of a therapeutic failure on or intolerance to one prior biologic therapy **AND**
- Medical record documentation of Tremfya 200 mg /20 mL vials for IV infusion are being prescribed for induction therapy at weeks 0, 4, and 8.

*Note: A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis.

AUTHORIZATION DURATION: One-time 3-month authorization (maximum of 3 visits for loading dose administration)

Tremfya (guselkumab) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

- Medical record documentation that Tremfya is prescribed by a gastroenterologist **AND**
- Medical record documentation of a diagnosis of moderately to severely active ulcerative colitis **AND**
- Medical record documentation that Tremfya is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of Tremfya 200 mg /20 mL vials for IV infusion are being prescribed for induction therapy at weeks 0, 4, and 8.

*Note: A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis.

AUTHORIZATION DURATION: One-time 3-month authorization (maximum of 3 visits for loading dose administration)

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:
1. Tremfya [prescribing information]. Horsham PA. Janssen Biotech, Inc. September 2024.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 10/18/24

Revised:

Reviewed:

MA UM Committee approval: 11/8/24