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Commercial/Healthcare Exchange PA Criteria

Effective: January 1, 2021

Prior Authorization: Tretinoin

Products Affected: Tretinoin oral capsule

<u>Medication Description</u>: Tretinoin appears to bind one or more nuclear receptors and decreases proliferation and induces differentiation of acute promyelocytic leukemia (APL) cells; initially produces maturation of primitive promyelocytes and repopulates the marrow and peripheral blood with normal hematopoietic cells to achieve complete remission.

<u>Covered Uses</u>: Indicated for the induction of remission in patients with acute promyelocytic leukemia, French-American-British (FAB) classification M3 (including the M3 variant), characterized by the presence of the t(15;17) translocation and/or the presence of the PML/RAR α gene who are refractory to, or who have relapsed from, anthracycline chemotherapy, or for whom anthracycline-based chemotherapy is contraindicated.

Exclusion Criteria:

- 1. Patients with a known hypersensitivity to tretinoin, any of its components, or other retinoids
- 2. Pregnancy

Required Medical Information:

- 1. Diagnosis
- 2. PML/RARα gene or t(15:17) translocation status
- 3. Previous therapies

Age Restrictions: N/A

Prescriber Restrictions: Prescribed by, or in consultation with, an oncologist or hematologist.

Coverage Duration: 3 years

Other Criteria:

- 1. Patient has a diagnosis of acute promyelocytic leukemia (APL); AND
- 2. Tretinoin is being used for the induction of remission; AND
- 3. Presence of t(15;17) translocation and/or the PML/RARα gene; AND
- 4. Previous therapy with anthracycline chemotherapy or a contraindication to use

<u>References</u>:

1. Tretinoin [Prescribing Information] Mahwah, NJ: Glenmark Pharmaceuticals Inc.; January 2016. Accessed December 7, 2020.

Policy Revision History:



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Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	1/1/2021



January 2021