Pharmacy Policy

Zokinvy

Policy Number: 9.340
Version Number: 1
Version Effective Date: 9/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☐ New Hampshire Medicaid	☐ MassHealth - MCO ☐ MassHealth - ACO ☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Zokinvy (lonafarnib)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	Not indicated for other Progeroid Syndroms or processing-proficient Progeroid Laminopathies
Required Medical Information	1. **Hutchinson-Gilford progeria syndrome (HGPS)** a. Documentation of confirmed diagnosis of Hutchinson-Gilford progeria syndrome (HGPS); **AND** b. Patient has a BSA of at least 0.39m^2; **AND** c. Requested dose is appropriate for patient's BSA. Documentation of BSA and proposed dosing regimen is required 2. **Processing-deficient progeroid laminopathy** a. Documentation of confirmed diagnosis of processing-deficient progeroid laminopahty with ONE of the following:

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	i. Heterozygous LMNA mutation with progerin-like protein accumulation ii. Homozygous or compound heterzygous ZMPSTE24 mutations; **AND** b. Patient has a BSA of at least 0.39m^2 ; **AND** c. Requested dose is appropriate for patient's BSA. Documentation of BSA and proposed dosing regimen is required
Age Restriction	12 months of age or older
Prescriber Restriction	Prescribed by or in consultation with a specialist in progeria, genetics or metabolic disorders
Coverage Duration	1 year
Other criteria	Reauthorization: 1. Member has responded positively to therapy 2. Requested dose is appropriate for member's BSA 3. Medication is continued to be prescribed by or in consultation with a specialist in progeria, genetics or metabolic disorders

Applicable Coding:

Clinical Background Information and References

1. Introne WJ et al. Hutchinson-Gilford progeria syndrome. UptoDate. Last updated January 25 2021. Accessed May 1 2021. Available from http://www.uptodate.com.
2. Zokinvy prescribing information. Eiger BioPharmaceuticals Inc. Palo Alto, CA. Accessed May 1 2021.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
5/13/2021	9/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**

Policy Revisions History			
5/13/2021	Policy created	9/1/2021	P&T Committee

Next Review Date

5/2022

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.