

Pharmacy Policy

Tukysa

Policy Number: 9.736

Version Number: 1.0

Version Effective Date: 9/1/2021

Product Applicability <input type="checkbox"/> All Plan+ Products	
<p>Well Sense Health Plan</p> <p><input type="checkbox"/> New Hampshire Medicaid</p>	<p>Boston Medical Center HealthNet Plan</p> <p><input type="checkbox"/> MassHealth - MCO</p> <p><input type="checkbox"/> MassHealth - ACO</p> <p><input checked="" type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct</p> <p><input type="checkbox"/> Senior Care Options</p>

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

Prior Authorization Policy

Products Affected:

- Tukysa (tucatinib)

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	Leptomeningeal disease
Required Medical Information	<ol style="list-style-type: none"> 1. Diagnosis of advanced unresectable or metastatic HER2-positive breast cancer; AND 2. The member has previously been treated with at least one anti-HER2-based regimen in the metastatic setting; AND 3. Tukysa will be used in combination with trastuzumab and capecitabine; AND 4. The requested dose does not exceed 300 mg twice daily

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Age Restriction	18 years and older
Prescriber Restriction	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other criteria	Reauthorization: 1. Initial criteria are met; AND 2. There has been no disease progression or unacceptable toxicity

Applicable Coding

Clinical Background Information and References

1. Tukysa (tucatinib) [prescribing information]. Seattle Genetics, Inc. Bothell, WA. April 2020.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
05/13/2021	9/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
5/13/2021	Policy created	9/1/2021	P&T Committee

Next Review Date

5/2022

Other Applicable Policies

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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.

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