TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Daklinza™ (daclatasvir)

Effective: August 3, 2017

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

This pharmacy medical necessity guideline applies to the following:	Fax Numbers:
Tufts Health Plan Commercial Plans ☐ Tufts Health Plan Commercial Plans – large group plans ☐ Tufts Health Plan Commercial Plans – small group and individual plans **Tufts Health Public Plans** ☐ Tufts Health Direct – Health Connector ☒ Tufts Health Together – A MassHealth Plan ☐ Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan **Tufts Health Freedom Plan products** ☐ Tufts Health Freedom Plan - large group plans ☐ Tufts Health Freedom Plan - small group plans	RXUM: 617.673.0988

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Daklinza (daclatasvir) is a hepatitis C virus (HCV) NS5A inhibitor indicated for use with sofosbuvir, with or without ribavirin, for the treatment of chronic HCV genotype 1 or 3 infection.

Sustained virologic response rates are reduced in genotype 3 patients with cirrhosis receiving Daklinza (daclatasvir) in combination with sofosbuvir for 12 weeks.

COVERAGE GUIDELINES

The plan may authorize coverage of Daklinza (daclatasvir) for Members when **all** the following criteria are met and limitations do not apply:

1. Documented diagnosis of chronic hepatitis C genotype 3

AND

2. Documented contraindication to or the provider has indicated clinical inappropriateness of treatment with Epclusa (sofosbuvir/velpatasvir)

AND

3. The member is at least 18 years of age

AND

4. Documentation of stage of hepatic fibrosis (e.g. F3 or F4) through one of the following:
   - Liver biopsy confirming a METAVIR score*
   - Transient elastography (Fibroscan) score
   - Fibrotest (FibroSURE) score
   - APRI score
   - Radiological imaging
   - Physical findings or clinical evidence attested by the prescribing physician

AND

4. Documentation Daklinza (datclatasvir) will be taken in combination with Sovaldi (sofosbuvir)

***Comparison of Scoring Systems for Histological Stage (Fibrosis)**

METAVIR	Batt-Ludwig	Knodell	Ishak
0	0	0	0
1	1	1	1
1	1	1	2
2	2	-	3
3	3	3	4

4	4	4	5
4	4	4	6

LIMITATIONS

1. The plan will not be covered Daklinza (daclatasvir) for members who are concurrently taking any medications that decrease the concentration of Daklinza (daclatasvir) (e.g. Strong inducers of CYP3A, including phenytoin, carbamazepine, rifampin, and St. John's wort)
2. Daklinza will be authorized for a maximum of 1 tablet per day.
3. Initial authorization will be as follows:
    a. Without Cirrhosis: Daklinza + sofosbuvir + ribavirin for 12 weeks
    b. Compensated Cirrhosis (Child-Pugh B or C): Daklinza + sofosbuvir + ribavirin for 12
    c. Decompensated Cirrhosis (Child-Pugh B or C): Daklinza + sofosbuvir + ribavirin for 12
    d. Post-Transplant: Daklinza + sofosbuvir + ribavirin for 12 weeks

CODES

None

REFERENCES

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APPROVAL HISTORY

July 12, 2016: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether
- August 3, 2017: Updated criteria to include documentation of a contraindication to or clinical inappropriateness with Epclusa (sofosbuvir/velpatasvir) based on the state Medicaid's current strategy for the treatment of Hepatitis C.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a member's benefit document and in coordination with the member's physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan members or to certain delegated service arrangements. Unless otherwise noted in the member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.