Effective: January 1, 2025

Prior Authorization Required If <u>REQUIRED,</u> submit supporting documentation pertinent to service request to the FAX clinical numbers below	Yes ☐ No ☒
Notification Required IF <u>REQUIRED,</u> concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; 800-232-0816

☒ Tufts Health Plan Commercial products; 617-972-9409

 CareLink^{SM} – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055

☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404

☒ Tufts Health One Care – A dual-eligible product; 857-304-6304

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; 866-874-0857

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-673-0965

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-673-0965

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-673-0965

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

Management of risk factors for cardiovascular disease (CVD) may be considered primary prevention for those who have not previously experienced an atherosclerotic vascular event, and there are several diagnostic tests designed to help assess non-traditional risk factors for cardiovascular disease.

Clinical Guideline Coverage Criteria

The Plan considers cardiovascular risk testing as reasonable and medically necessary when used to predict the risk of recurrent events in those with coronary artery disease (CAD) so that applicable interventions can be introduced and improved.

Limitations

The Plan does not cover the following as they are non-covered or investigational due to insufficient evidence of efficacy:
1. Advanced and novel lipoprotein analysis (subfractions, apolipoproteins,) for evaluation of cardiovascular risk

2. Multi-protein diagnostic biomarker, such as 3 proteins (high sensitivity [hs] troponin, adiponectin, and kidney injury molecule-1 [KIM-1]) or 4 proteins (NT-proBNP, osteopontin, tissue inhibitor of metalloproteinase-1 [TIMP-1], and KIM-1) with algorithm and reported as a risk score
3. Cardiovascular disease risk panels, consisting of multiple individual biomarkers intended to assess cardiac risk to include lipid and non-lipid cardiovascular risk markers such as:
    a. Long-chain omega-3 fatty acids for cardiovascular risk testing
    b. LDL subclass (e.g., Boston Heart Cholesterol Balance® Test)
    c. Lipoprotein (e.g., direct measurement, intermediate density lipoproteins (IDL) remnant lipoproteins)
    d. Lipoprotein- associated phospholipase (LP-PLA$_2$)
4. Arterial compliance testing using waveform analysis to determine cardiovascular risk
5. Carotid intima-media thickness (CIMT) measurement
6. Endothelial function assessment tools (e.g., peripheral arterial tonometry, brachial artery pressure ultrasound)

Please refer to the Noncovered and Investigational Services MNG

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Approval And Revision History

December 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC) for integration between Harvard Pilgrim Health Care and Tufts Health Plan. Coverage guideline created to outline medical necessity for cardiovascular disease risk tests. Effective July 7, 2023
Subsequent endorsement date(s) and changes:

- November 16, 2023: Reviewed by MPAC, renewed without changes
- November 2023: Unify name changed to One Care effective January 1, 2024
- November 21, 2024: Reviewed by MPAC, renewed without changes, effective January 1, 2025
- December 13, 2024: Reviewed and approved by the UM Committee, effective January 1, 2025

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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