OVERVIEW
Esbriet is indicated for the treatment of idiopathic pulmonary fibrosis (IPF). The recommended daily maintenance dose of Esbriet is 801 mg (three 267-mg capsules) three times a day (TID) with food for a total of 2,403 mg/day. Doses should be administered at the same time each day. Dosages above 2,403 mg/day (nine capsules per day) are not recommended. Upon treatment initiation, titrate to the full dosage of nine capsules per day over a 14-day period. Liver function tests (LFTs) should be performed prior to Esbriet initiation.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Esbriet is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. Idiopathic Pulmonary Fibrosis (IPF). Approve if the patient meets the following criteria (a, b, c and d).
   a) The patient is aged ≥ 40 years; AND
   b) The agent has been prescribed by, or in consultation with, a pulmonologist; AND
   c) At baseline (before therapy initiation), patients have an FVC ≥ 50% of the predicted value; AND
   d) The diagnosis of IPF is confirmed by one of the following (i or ii):
      i. Findings on high-resolution computed tomography (HRCT) indicates usual interstitial pneumonia (UIP); OR
      ii. A surgical lung biopsy demonstrates usual interstitial pneumonia (UIP).

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Esbriet has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. Esbriet is Being Used Concomitantly with Ofev® (nintedanib capsules). Ofev is another medication indicated for the treatment of IPF. The effectiveness and safety of concomitant use of Esbriet with Ofev have not been established.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.
Approval Duration: 365 days (1 year)

References