

The drug, Aubagio® (teriflunomide), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must have a negative tuberculosis skin test [such as Tuberculin PPD (purified protein derivative) test] or Interferon-Gamma Release Assay (IGRA) whole-blood test [such as QuantiFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.TB test (T-Spot)]
- Must be prescribed by or in consultation with a neurologist
- Must be age 18 years or older
- Must have a diagnosis of relapsing form of multiple sclerosis
- Must have a negative pregnancy test within 1 month of treatment initiation with Aubagio (date of test must be submitted) and must be using reliable contraception during treatment if of childbearing potential
- Must have recent (within 6 months) transaminase and bilirubin levels
- Must have recent (within 6 months) Complete Blood Count (CBC)
- Must not have severe hepatic impairment
- Must have no evidence of active infection
- Must not be on concomitant therapy with antineoplastic, immunosuppressive, or immune modulating therapies

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon:

- Documentation from the provider that the member's disease course has stabilized or improved based upon the prescriber's assessment while on therapy
- Documentation that the member's transaminase/ bilirubin levels are being monitored consistently
- Documentation that there is no evidence of active infection
- Documentation that the member is not on concomitant therapy with antineoplastic, immunosuppressive, or immune modulating therapies

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Up to 1 year
Quantity Level Limit	
Tablet	30 tablets per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Aubagio [package insert]. Cambridge, MA: Genzyme Corporation; September 2012
2. O’Conner P, Wolinsky JS, Confavreux C, et al. Randomized trial of oral teriflunomide for relapsing multiple sclerosis. N Engl J Med 2011; 365:1293-303
3. Killestein J, Rudick RA, Polman C. Oral treatment for multiple sclerosis. Lancet Neurol 2011;10:1026-34
4. Fox EJ, Rhoades RW. New treatments and treatment goals for patients with relapsing-remitting multiple sclerosis. Curr Opin Neurol 2012;25(suppl 1);S11-S19
5. Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis infection – United States 2010. Department of Health and Human Services Centers for Disease Control and Prevention [U.S.]. vol 59, RR-5. 2010 June 25.
6. Interferon-Gamma Release Assays (IGRAs) – Blood Tests for TB Infection. <http://www.cdc.gov/tb/publications/factsheets/testing/IGRA.htm>. Accessed 10/29/2012.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	02/16, 02/17, 02/18
Criteria update	10/16, 12/17 09/18 (eff 1/19)