

| Market Applicability | | | | | | | | | | | | | | | |
|----------------------|----|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|
| Market | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
| Applicable | X | X | NA | NA | X | NA | X | X | X | X | X | X | NA | NA | NA |

*FHK- Florida Healthy Kids

Aubagio (teriflunomide)

| Override(s) | Approval Duration |
|---------------------------------------|-------------------|
| Prior Authorization Quantity Limit | 1 year |

| Medications | Quantity Limit |
|---|----------------------------------|
| Aubagio (teriflunomide) – all strengths | May be subject to quantity limit |

APPROVAL CRITERIA

Requests for Aubagio (teriflunomide) may be approved when the following criteria are met:

- I. Individual has a diagnosis of relapsing-remitting multiple sclerosis (RRMS);

AND

- II. Individual has been on Aubagio (teriflunomide); **OR**
- III. Individual has had a trial and inadequate response or intolerance to one of the following:
 - A. Avonex (interferon beta-1a); **OR**
 - B. Rebif (interferon beta-1a); **OR**
 - C. Betaseron (interferon beta-1b); **OR**
 - D. Extavia (interferon beta1-1b); **OR**
 - E. Tecfidera (dimethyl fumarate); **OR**
 - F. Glatopa (glatiramer) 20mg; **OR**
 - G. Glatiramer 20mg.

Aubagio (teriflunomide) may **not** be approved for the following:

- I. Concurrent use with other MS disease modifying agents (such as Gilenya, Tecfidera, Tysabri, Lemtrada, Zinbryta, Copaxone/Glatopa, Extavia, Rebif, Avonex, Plegridy, or Betaseron); **OR**
- II. Individual has a diagnosis of severe hepatic impairment (Child-Pugh Class C); **OR**
- III. Concurrent use with leflunomide (Arava); **OR**
- IV. Individual has an active acute or chronic infection at the initiation of therapy; **OR**
- V. Individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC)-recommended equivalent to evaluate for latent tuberculosis prior to initiation of therapy.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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| Market | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
| Applicable | X | X | NA | NA | X | NA | X | X | X | X | X | X | NA | NA | NA |

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Requests for a quantity greater than the limit will be reviewed on a case by case basis.

Note: Aubagio (teriflunomide) has black box warnings for hepatotoxicity and risk of teratogenicity. It has been noted that severe liver injury, including fatal liver failure, has occurred in individuals treated with leflunomide. Because of this, there is a similar risk expected for Aubagio because of similar range of doses and plasma concentrations compared to leflunomide. Transaminase and bilirubin levels should be obtained within 6 months before initiation of therapy. ALT levels should be monitored at least monthly for 6 months. If liver injury is suspected, therapy should be discontinued and accelerated elimination procedure should be initiated. In addition, there is a risk of major birth defects associated with Aubagio resulting in a contraindication in pregnant women or women of childbearing potential who are not using reliable contraception.

| State Specific Mandates | | |
|-------------------------|----------------|---|
| State name | Date effective | Mandate details (including specific bill if applicable) |
| N/A | N/A | N/A |

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>
Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed on: January 30, 2017.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2015; Updated periodically.

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