Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

Aubagio (teriflunomide)

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

Medications	Quantity Limit
Aubagio (teriflunomide)	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 multiple sclerosis (RMS);

AND

II. Individual has been on Aubagio (teriflunomide); **OR**

III. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one of the following:

A. One preferred beta interferon agent:

1. Avonex (interferon beta-1a); **OR**
2. Betaseron (interferon beta-1b); **OR**
3. Extavia (interferon beta1-1b); **OR**
4. Rebif (interferon beta-1a);

OR

B. Tecfidera (dimethyl fumarate);

OR

C. Glatopa (glatiramer) or glatiramer.

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

I. Concurrent use with other MS disease modifying agents (including Avonex, Betaseron, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Rebif, Tecfidera and Tysabri); **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**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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.

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:

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