Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	N/A

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Ocrevus (ocrelizumab)

DRUG.00095

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Ocrevus (ocrelizumab)

APPROVAL CRITERIA

Requests for Ocrevus (ocrelizumab) may be approved for treatment of primary progressive multiple sclerosis (PPMS) or relapsing multiple sclerosis (RMS) when the following criteria are met:

I. Individual has a diagnosis of primary progressive multiple sclerosis (PPMS) in accordance with the McDonald Criteria; **AND**
II. Individual is able to ambulate more than 5 meters (not considered wheelchair bound); **OR**
III. Individual has a diagnosis of relapsing multiple sclerosis (RMS) in accordance with the McDonald Criteria; **AND**
IV. Individual is able to ambulate without aid or rest for at least 100 meters; **AND**
V. Individual is 18 years of age or older.

Requests for Ocrevus (ocrelizumab) may not be approved as a treatment for PPMS or RMS when either of the following contraindications (I. or II. below) is present, or when criteria above are not met, or for indications in III.-VI. below:

I. Diagnosis of active hepatitis B or hepatitis C virus infection; **OR**
II. A history of life-threatening infusion reaction to ocrelizumab; **OR**
III. Treatment of secondary progressive multiple sclerosis; **OR**
IV. Individuals with a relapsing form of MS who have not experienced at least two relapses as defined by the McDonald Criteria within the previous 2 years, or one relapse within the previous year; **OR**
V. Systemic lupus erythematosus; **OR**
VI. Rheumatoid arthritis.

Requests for Ocrevus (ocrelizumab) may not be approved as a treatment for RMS or PPMS when the criteria above are not met and for all other indications, including but not limited to treatment for secondary progressive multiple sclerosis.

Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	N/A

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

Key References:

1. Hoffmann-La Roche. A study of ocrelizumab in comparison with Interferon Beta-1a (Rebif) in participants with relapsing multiple sclerosis: OPERA I. NLM Identifier: NCT01412333. Updated October 25, 2016. Available at: https://clinicaltrials.gov/ct2/show/NCT01412333. Accessed on June 29, 2017.
2. Hoffmann-La Roche. A study of ocrelizumab in comparison with Interferon Beta-1a (Rebif) in participants with relapsing multiple sclerosis: OPERA II. NLM Identifier: NCT01247324. Updated October 10, 2016. Available at: https://clinicaltrials.gov/ct2/show/NCT01247324. Accessed on June 29, 2017.
3. Hoffmann-La Roche. A study of ocrelizumab in patients with primary progressive multiple sclerosis. NLM Identifier: NCT01194570. Updated January 6, 2017. Available at: https://clinicaltrials.gov/ct2/show/NCT01194570. Accessed on June 29, 2017.
4. Ocrevus™. Product Information Label. Genentech, Inc, San Francisco, CA. Updated March 28, 2017. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761053lbl.pdf. Accessed on June 29, 2017.

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.