



Multiple Sclerosis Drugs

Ocrevus (ocrelizumab) J2350, Copaxone (Glatiramer acetate) J1595, Zenapax (daclizumab) J7513, Briumvi (ublituximab) J2329, Tyruko (natalizumab-sztn) Q5134, are Non-preferred. The preferred products are Part D alternatives including Aubagio and generic glatiramer (See Part D Formulary, no PA required for most preferred Part D alts).
Prior Authorization Step Therapy Request
Medicare Part B Form

Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

Self-administered Provider-administered Home Infusion

Chart notes attached. Other important information: _____

Diagnosis: ICD10: _____ **Description:** _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)

Tyruko (Q5134)

Diagnosis of relapsing multiple sclerosis (RMS) (including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease); AND

Patient enrolled in and meeting all conditions of the MS Touch Prescribing Program; OR

Diagnosis of moderate to severe Crohn's disease (CD) and is using Tysabri/Tyruko for induction and maintenance of clinical response and remission; AND

Individual has had an inadequate response to or is unable to tolerate conventional Crohn's disease therapies and TNF-α inhibitors; AND

Patient enrolled in and meeting all conditions of the CD Touch Prescribing Program; AND

Patient has had a John Cuninghnam virus (JCV) antibody test and the results as well as risks and benefits have been discussed and understood.

All Other Drugs - Provider has reviewed the attached “Criteria for Approval” and attests the member meets ALL required PA criteria.

If not, please provide **clinical rationale** for formulary exception: _____

Continuation Requests: (Clinical documentation required for all requests)

Provider has reviewed the attached “Criteria for Continuation” and attests the member meets ALL required PA Continuation criteria.

Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Multiple Sclerosis Drugs PA

Drug Name(s):

OCREVUS	OCRELIZUMAB
COPAXONE	GLATIRAMER ACETATE
ZENAPAX	DACLIZUMAB
BRIUMVI	UBLITUXIMAB
TYRUKO	NATALIZUMAB-SZTN

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approvals will be for 12 months

FDA Indications:

Ocrevus

- Multiple sclerosis, Relapsing forms
- Primary progressive multiple sclerosis

Copaxone, Briumvi

- Multiple sclerosis, Relapsing forms

Tyruko

- Crohn's disease (Moderate to Severe), Previous inadequate response to, or unable to tolerate, conventional therapies and tumor necrosis factor-alpha inhibitors
- Multiple sclerosis, Relapsing forms, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; monotherapy

Zenapax

- The worldwide marketing and distribution of Zinbryta(R) (daclizumab) was voluntarily discontinued on March 2, 2018 due to safety concerns

Off-Label Uses:

N/A

Age Restrictions:

Safety and effectiveness of ocrelizumab have not been established in pediatric patients

Other Clinical Considerations:

Ocrevus

- Active hepatitis B virus infection

Tyruko

- History of or active progressive multifocal leukoencephalopathy

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/9E37E3/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/5D1C03/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=ocrelizumab&UserSearchTerm=ocrelizumab&SearchFilter=filterNone&navitem=searchGlobal#

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