

Request for Prior Authorization for Natalizumab Website Form – <u>www.wv.highmarkhealthoptions.com</u> Submit request via: Fax - 1-833-547-2030.

All requests for Natalizumab require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

## Natalizumab Prior Authorization Criteria:

For all requests for Natalizumab all of the following criteria must be met:

- Member must be 18 years of age or older
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Prescribed the requested medication by or in consultation with an appropriate specialist (i.e., a neurologist for a diagnosis of multiple sclerosis or a gastroenterologist for a diagnosis of Crohn's disease)
- Does not have a contraindication to the requested medication
- Is not receiving chronic immunosuppressant or immunomodulator therapy

Coverage may be provided with a diagnosis of <u>relapsing forms of multiple sclerosis</u> (e.g. relapsing-remitting, secondary-progressive, or clinically isolated syndrome) and the following criteria are met:

- The drug is given as monotherapy and not in combination with other therapies approved for the treatment of MS
- Patients initiating therapy for the <u>first time</u> must have at least one clinical relapse documented (e.g., functional disability, hospitalization, acute steroid therapy, etc.) during the prior year
- Member must have documented Expanded Disability Status Scale (EDSS) score of 5.0 or lower
- Initial Duration of Approval: 6 months
- Reauthorization criteria
  - Documentation of a clinical response defined as:
    - No increase in their Expanded Disability Status Scale (EDSS) score
    - No relapse rate increase or >1 relapse per year after at least 6 months of treatment
- Reauthorization Duration of approval: 12 months

Coverage may be provided with a diagnosis of <u>moderate to severe Crohn's disease</u> and the following criteria are met:

- Documentation of C-reactive protein >2.87 mg/L (evidence of inflammation) and baseline Crohn's Disease Activity Index (CDAI) ≥220 (moderate to severe disease)
- Must meet one of the following:
  - Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids OR
  - $\circ$  One of the following:
    - (i) Failed to maintain remission with an immunomodulator in accordance with current consensus guidelines<sup>2</sup>



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- (ii) Has a contraindication or an intolerance to immunomodulators in accordance with current consensus guidelines<sup>2</sup>
- Has a diagnosis of Crohn's disease that is associated with one or more highrisk or poor prognostic features<sup>3</sup>
- Must meet one of the following:
  - (i) Has a history of therapeutic failure of at least 1 tumor necrosis factor (TNF) inhibitor indicated or medically accepted for the treatment of Crohn's disease
  - (ii) Has a contraindication or an intolerance to the TNF inhibitors indicated or medically accepted for the treatment of Crohn's disease
- Initial Duration of Approval: 6 months
- Reauthorization criteria
  - Documentation of a clinical response such as a decrease in CDAI from baseline
- **Reauthorization Duration of approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.



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| NATALIZUMAB<br>PRIOR AUTHORIZATION FORM  |  |   |   |  |  |
|--|--|---|---|--|--|
| Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation  |  |   |   |  |  |
| as applicable to Highmark Health Options Pharmacy Services. FAX: (833)-547-2030.   |  |   |   |  |  |
| If needed, you may call to speak to a Pharmacy Services Representative. PHONE: 1-844-325-6251 Mon - Fri 8 am to 7 pm   |  |   |   |  |  |
|  | PROVIDER 1   | NFORMATION  |   |  |  |
| Requesting Provider:   |  | NPI:  |   |  |  |
| Provider Specialty:  | Office C   |   |   |  |  |
| Office Address:  |  | Office Pho  |   |  |  |
|  |  | Office Fax  |   |  |  |
| Member Name:   | MEMBER I   | NFORMATION<br>DOB:  |   |  |  |
| Member ID:   |  | Member weight:  | Height:                                     |  |  |
| Member ID.   | DEALIESTEN ND  | UG INFORMATION  | Tielgiit.                                   |  |  |
| Medication:  | KEQUESTED DK   | Strength:   |   |  |  |
| Directions:  |  | Quantity:   | Refills:                                    |  |  |
| Is the member currently receiving rec  | uested medication?  Yes  |   | Aedication Initiated:                       |  |  |
|  |  |   | ion may be necessary for the life of the    |  |  |
| patient? $\Box$ Yes $\Box$ No  |  | million the mealeur   |   |  |  |
|  | Billing I  | nformation  |   |  |  |
| This medication will be billed:  |  | ically, JCODE:  |   |  |  |
| Place of Service: Hospital   | Provider's office 🗌 Memb   | per's home 🗌 Other  |   |  |  |
|  | Place of Serv  | ice Information   |   |  |  |
| Name:  |  | NPI:  |   |  |  |
| Address:   |  | Phone:  |   |  |  |
|  |  |   |   |  |  |
|  | MEDICAL HIGTODY (  | Commisto for ATT  |   |  |  |
| Diagnosis  | MEDICAL HISTORY (  |   | uests)                                      |  |  |
| Diagnosis:   |  | Complete for ALL req<br>ICD Code:   | uests)                                      |  |  |
| For relapsing forms of multiple scl  | erosis   | ICD Code:   |   |  |  |
| <b>For relapsing forms of multiple scl</b><br>Is the member receiving chronic imm  | erosis<br>nunosuppressant or immuno  | ICD Code:   |   |  |  |
| For relapsing forms of multiple scl<br>Is the member receiving chronic imm<br>Will this be given as monotherapy?   | erosis<br>nunosuppressant or immunc<br>] Yes ] No  | ICD Code:   |   |  |  |
| For relapsing forms of multiple scle<br>Is the member receiving chronic imm<br>Will this be given as monotherapy? [<br>Is the member initiating therapy for t  | erosis<br>nunosuppressant or immunc<br>] Yes ] No<br>he first time? ] Yes ] N  | ICD Code:<br>modulator therapy?   |   |  |  |
| For relapsing forms of multiple scle<br>Is the member receiving chronic imm<br>Will this be given as monotherapy? [<br>Is the member initiating therapy for t<br>Has the member had at least one clim  | erosis<br>nunosuppressant or immunc<br>] Yes   No<br>he first time?   Yes   No<br>ical relapse?   Yes   No   | ICD Code:   |   |  |  |
| For relapsing forms of multiple scle<br>Is the member receiving chronic imm<br>Will this be given as monotherapy? [<br>Is the member initiating therapy for t  | erosis<br>nunosuppressant or immunc<br>] Yes   No<br>he first time?   Yes   No<br>ical relapse?   Yes   No   | ICD Code:   |   |  |  |
| For relapsing forms of multiple scle<br>Is the member receiving chronic imm<br>Will this be given as monotherapy? [<br>Is the member initiating therapy for the<br>Has the member had at least one climate<br>What is the member's Expanded Disa   | erosis<br>nunosuppressant or immuno<br>] Yes D No<br>he first time? Yes No<br>ical relapse? Yes No<br>ability Status Scale (EDSS)  | ICD Code:   |   |  |  |
| For relapsing forms of multiple scle<br>Is the member receiving chronic imm<br>Will this be given as monotherapy? [<br>Is the member initiating therapy for the<br>Has the member had at least one climic<br>What is the member's Expanded Disa<br>For moderate to severe Crohn's disa   | erosis<br>nunosuppressant or immuno<br>] Yes   No<br>he first time?   Yes   No<br>ical relapse?   Yes   No<br>ability Status Scale (EDSS)<br>sease   | ICD Code:   |   |  |  |
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| For relapsing forms of multiple scle<br>Is the member receiving chronic imm<br>Will this be given as monotherapy? [<br>Is the member initiating therapy for the<br>Has the member had at least one climic<br>What is the member's Expanded Disa<br>For moderate to severe Crohn's disa   | erosis<br>munosuppressant or immuno<br>Yes No<br>he first time? Yes No<br>ical relapse? Yes No<br>ability Status Scale (EDSS)<br>sease<br>ein level?   | ICD Code:   |   |  |  |
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| For relapsing forms of multiple scla<br>Is the member receiving chronic imm<br>Will this be given as monotherapy? [<br>Is the member initiating therapy for t<br>Has the member had at least one clim<br>What is the member's Expanded Disa<br>For moderate to severe Crohn's dis<br>What is the members C-reactive prote<br>What is the member's baseline Crohr<br>Mark all that apply to the member:<br>Failed to achieve remission with o   | erosis<br>nunosuppressant or immuno<br>Yes No<br>he first time? Yes No<br>ical relapse? Yes No<br>ability Status Scale (EDSS)<br>sease<br>ein level?<br>n's Disease Activity Index?<br>pr has a contraindication or a  | ICD Code:   | Yes  No |  |  |
| For relapsing forms of multiple scla<br>Is the member receiving chronic imm<br>Will this be given as monotherapy? [<br>Is the member initiating therapy for the<br>Has the member had at least one climic<br>What is the member's Expanded Disa<br>For moderate to severe Crohn's disa<br>What is the members C-reactive protocom<br>What is the member's baseline Crohn<br>Mark all that apply to the member:<br>Failed to achieve remission with<br>Failed to maintain remission with  | erosis<br>nunosuppressant or immuno<br>Yes No<br>he first time? Yes No<br>ical relapse? Yes No<br>ability Status Scale (EDSS)<br>sease<br>ein level?<br>n's Disease Activity Index?<br>pr has a contraindication or an<br>n an immunomodulator in ac   | ICD Code:<br>modulator therapy?   | Yes No                                      |  |  |
| For relapsing forms of multiple scla<br>Is the member receiving chronic imm<br>Will this be given as monotherapy? [<br>Is the member initiating therapy for the<br>Has the member had at least one climic<br>What is the member's Expanded Disa<br>For moderate to severe Crohn's disa<br>What is the members C-reactive protonor<br>What is the member's baseline Crohn<br>Mark all that apply to the member:<br>Failed to achieve remission with<br>Failed to maintain remission with<br>Has a contraindication or an intol  | erosis<br>nunosuppressant or immuno<br>Yes No<br>he first time? Yes No<br>ical relapse? Yes No<br>ability Status Scale (EDSS)<br>sease<br>ein level?<br>n's Disease Activity Index?<br>pr has a contraindication or an<br>n an immunomodulator in ac<br>lerance to immunomodulator   | ICD Code:         modulator therapy?         io         io         score?         an intolerance to an induce to an induce with current or sin accordance with current or sin accord | Yes No                                      |  |  |
| For relapsing forms of multiple scla<br>Is the member receiving chronic imm<br>Will this be given as monotherapy? [<br>Is the member initiating therapy for the<br>Has the member had at least one climin<br>What is the member's Expanded Disa<br>For moderate to severe Crohn's disa<br>What is the member's baseline Crohn<br>What is the member's baseline Crohn<br>Mark all that apply to the member:<br>Failed to achieve remission with the<br>Failed to maintain remission with<br>Has a contraindication or an intol<br>Has a diagnosis of Crohn's diseas   | erosis<br>nunosuppressant or immuno<br>Yes No<br>he first time? Yes No<br>ical relapse? Yes No<br>ability Status Scale (EDSS)<br>sease<br>ein level?<br>n's Disease Activity Index?<br>or has a contraindication or a<br>n an immunomodulator in ac<br>lerance to immunomodulator<br>se that is associated with one  | ICD Code:         modulator therapy?         io  | Yes No                                      |  |  |
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| For relapsing forms of multiple scla<br>Is the member receiving chronic imm<br>Will this be given as monotherapy? [<br>Is the member initiating therapy for t<br>Has the member had at least one clim<br>What is the member's Expanded Disa<br>For moderate to severe Crohn's dis<br>What is the member's baseline Crohn<br>What is the member's baseline Crohn<br>Mark all that apply to the member:<br>Failed to achieve remission with<br>Failed to maintain remission with<br>Has a contraindication or an intol<br>Has a diagnosis of Crohn's diseas<br>Has a history of therapeutic failur<br>treatment of Crohn's disease   | erosis<br>nunosuppressant or immuno<br>Yes No<br>he first time? Yes No<br>ical relapse? Yes No<br>ability Status Scale (EDSS)<br>sease<br>ein level?<br>or has a contraindication or a<br>n an immunomodulator in ac<br>lerance to immunomodulator<br>we that is associated with one<br>e of at least 1 tumor necrosi<br>erance to the TNF inhibitors                                | ICD Code:         modulator therapy?         modulator therapy?         io         io         score?         man intolerance to an inductor         cordance with current or         rs in accordance with current or         or more high-risk or point         s factor (TNF) inhibitor         indicated or medically  | Yes No                                      |  |  |
| For relapsing forms of multiple scla<br>Is the member receiving chronic imm<br>Will this be given as monotherapy? [<br>Is the member initiating therapy for t<br>Has the member had at least one clim<br>What is the member's Expanded Disa<br>For moderate to severe Crohn's dis<br>What is the member's Expanded Disa<br>What is the member's Expanded Disa<br>What is the member's Expanded Disa<br>What is the member's baseline Crohn's disa<br>What is the member's baseline Crohn<br>Mark all that apply to the member:<br>Failed to achieve remission with<br>Has a contraindication or an into<br>Has a diagnosis of Crohn's disease<br>Has a history of therapeutic failur<br>treatment of Crohn's disease<br>Has a contraindication or an intole<br>disease | erosis<br>nunosuppressant or immund<br>Yes No<br>he first time? Yes No<br>ical relapse? Yes No<br>ability Status Scale (EDSS)<br>sease<br>ein level?<br>n's Disease Activity Index?<br>or has a contraindication or a<br>n an immunomodulator in ac<br>lerance to immunomodulator<br>te that is associated with one<br>e of at least 1 tumor necrosi<br>erance to the TNF inhibitors | ICD Code:         modulator therapy?         io         io         score?         an intolerance to an induce         in accordance with current or         in accordance with current or         io more high-risk or post         indicated or medically         EVIOUS THERAPY   | Yes No                                      |  |  |
| For relapsing forms of multiple scla<br>Is the member receiving chronic imm<br>Will this be given as monotherapy? [<br>Is the member initiating therapy for t<br>Has the member had at least one clim<br>What is the member's Expanded Disa<br>For moderate to severe Crohn's dis<br>What is the member's Expanded Disa<br>What is the member's baseline Crohn's disa<br>What is the member's baseline Crohn's<br>Mark all that apply to the member:<br>Failed to achieve remission with<br>Has a contraindication or an intol<br>Has a history of therapeutic failur<br>treatment of Crohn's disease<br>Has a contraindication or an intol  | erosis<br>nunosuppressant or immuno<br>Yes No<br>he first time? Yes No<br>ical relapse? Yes No<br>ability Status Scale (EDSS)<br>sease<br>ein level?<br>or has a contraindication or a<br>n an immunomodulator in ac<br>lerance to immunomodulator<br>we that is associated with one<br>e of at least 1 tumor necrosi<br>erance to the TNF inhibitors                                | ICD Code:         modulator therapy?         modulator therapy?         io         io         score?         man intolerance to an inductor         cordance with current or         rs in accordance with current or         or more high-risk or point         s factor (TNF) inhibitor         indicated or medically  | Yes No                                      |  |  |



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| NATALIZ<br>PRIOR AUTHORIZATION FORM  |                            | 2 OF 2                         |  |  |
|--|----------------------------|--------------------------------|--|--|
| Please complete and fax all requested information below including a  |                            |                                |  |  |
| as applicable to Highmark Health Options Ph  | narmacy Services. FAX: (83 | 3)-547-2030.                   |  |  |
| If needed, you may call to speak to a Pharmacy Services Repres   | sentative. PHONE: 1-844-3  | 25-6251 Mon – Fri 8 am to 7 pm |  |  |
| MEMBER INFORMATION   |                            |                                |  |  |
| Member Name:   | DOB:                       |                                |  |  |
| Member ID:   | Member weight:             | Height:                        |  |  |
| REAUTHORIZATION  |                            |                                |  |  |
| For relapsing forms of multiple sclerosis  |                            |                                |  |  |
| Has the member experienced a clinical response since starting treatment such as no increase in their EDSS score or no relapse or less than 1 relapse per year? baseline Yes No (please provide documentation). |                            |                                |  |  |
| For moderate to severe Crohn's disease<br>Has the member experienced a clinical response such as a decrease in CDAI from baseline Yes No (please provide<br>documentation).                                    |                            |                                |  |  |
|  |                            |                                |  |  |
|  |                            |                                |  |  |
|  |                            |                                |  |  |
| Prescribing Provider Signature   |                            | Date                           |  |  |
|  |                            |                                |  |  |