aetna™

MEDICARE FORM

Inflectra® (infliximab-dyyb) Injectable Medication Precertification Request

(All fields must be completed and legible for Precertification Review.)

For Virginia HMO SNP:
FAX: 1-833-280-5224
PHONE: 1-855-463-0933

For other lines of business:
Please use other form.

Note: Inflectra is non preferred. Renflexis is preferred for MA plans and Humira is preferred for MAPD plans.

Please indicate: ☐ Start of treatment: Start date ____/____/____
☐ Continuation of therapy: Date of last treatment ____/____/____

Precertification Requested By: _____ Phone: _____ Fax: _____

A. PATIENT INFORMATION

First Name:	Last Name:		
Address:	City:	State:	ZIP:
Home Phone:	Work Phone:	Cell Phone:	
DOB:	Allergies:	Email:	

Current Weight: _____ lbs or _____ kgs Height: _____ inches or _____ cms

B. INSURANCE INFORMATION

Aetna Member ID #: _____
Group #: _____
Insured: _____

Does patient have other coverage? ☐ Yes ☐ No
If yes, provide ID#: _____ Carrier Name: _____
Insured: _____

C. PRESCRIBER INFORMATION

First Name:		Last Name: *(Check One):* ☐ M.D. ☐ D.O. ☐ N.P. ☐ P.A.			
Address:		City:		State:	ZIP:
Phone:	Fax:	St Lic #:	NPI #:	DEA #:	UPIN:
Office Contact Name:				Phone:	

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Place of Administration:
☐ Self-administered ☐ Physician's Office
☐ Outpatient Infusion Center Phone: _____
Center Name: _____
☐ Home Infusion Center Phone: _____
Agency Name: _____
☐ Administration code(s) (CPT): _____
Address: _____

Dispensing Provider/Pharmacy:
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Pharmacy ☐ Other: _____
Name: _____
Address: _____
Phone: _____ Fax: _____
TIN: _____ PIN: _____

E. PRODUCT INFORMATION – Please select the medication being requested

Request is for: Inflectra (infliximab-dyyb) Dose: _____ **Frequency:** _____ **HCPCS Code:** _____

F. DIAGNOSIS INFORMATION – Please indicate primary ICD Code and specify any other where applicable.

Primary ICD Code: _____ Secondary ICD Code: _____ Other ICD Code: _____

G. CLINICAL INFORMATION – Required clinical information must be completed in its entirety for all precertification requests.

For Initiation Requests (clinical documentation required for all requests):

Note: Inflectra is non preferred. Renflexis is preferred for MA products or Humira is preferred for MAPD products.

☐ Yes ☐ No Has the patient had prior therapy with Inflectra (infliximab-dyyb) within the last 365 days?
☐ Yes ☐ No Has the patient had a trial, intolerance, or contraindication to Renflexis (infliximab-abda)?
☐ Yes ☐ No Has the patient had a trial, intolerance, or contraindication to Humira (adalimumab)?
Please explain if there are any other medical reason(s) that the patient cannot use Renflexis (infliximab-abda).

_____

Please explain if there are any other medical reason(s) that the patient cannot use Humira (adalimumab).

_____

☐ Yes ☐ No Will Inflectra (infliximab-dyyb) be used concomitantly with apremilast, tofacitinib, or other biologic DMARDs (e.g., adalimumab, certolizumab)?
☐ Yes ☐ No Has the patient been tested for TB with a PPD test, interferon-release assay (IGRAs) or chest x-ray within 6 months of initiation a biologic therapy?
→ (check all that apply): ☐ PPD test ☐ interferon-gamma assay (IGRA) ☐ chest x-ray
Please enter results of the TB test: ☐ positive ☐ negative ☐ unknown
If positive, Does the patient have latent or active TB? ☐ latent ☐ active
If latent TB, ☐ Yes ☐ No Will TB treatment be started before initiation of therapy with Inflectra (infliximab-dyyb)?
☐ Yes ☐ No Is this infusion request in an outpatient hospital setting?
→ ☐ Yes ☐ No Is the patient medically unstable for infusions at alternate levels of care?
☐ Yes ☐ No Does the patient have a history of any cardiopulmonary conditions?
→ Please provide the description of the condition: _____
☐ Yes ☐ No Does this condition cause an increased risk of severe adverse reactions?
☐ Yes ☐ No Does the patient have documentation of unstable vascular access?
☐ Yes ☐ No Does the patient have physical or cognitive impairments such that home infusion would present an unnecessary health risk?
→ Please explain: _____

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G. CLINICAL INFORMATION *(continued)* – Required clinical information must be completed in its entirety for all precertification requests.

☐ Yes ☐ No Is there clinical evidence that the patient has an inability to safely tolerate intravenous volume load (including from unstable renal function)?
→ ☐ Yes ☐ No Is the inability to tolerate intravenous volume load due to unstable renal function?
→ Please document the following: ☐ GFR: _____ mL/min/1.73m^2 Date Collected: ____/____/____
☐ BUN: _____ mg/dL Date Collected: ____/____/____
☐ Creatinine: _____ mg/dL Date Collected: ____/____/____

Ankylosing Spondylitis and Other Spondyloarthropathies
Please select which of the following applies to the patient: ☐ Ankylosing spondylitis ☐ Other spondyloarthropathy
☐ Yes ☐ No Is there evidence that the disease is active?
☐ Yes ☐ No Is there evidence of inflammatory disease?
☐ Yes ☐ No Has the patient had an ineffective response to two or more non-steroidal anti-inflammatory drugs (NSAIDs)?
→ Please provide the names and length of treatment:
NSAID #1: _____
Please indicate length of treatment: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater
NSAID #2: _____
Please indicate length of treatment: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater

Behcet's Disease
☐ Yes ☐ No Is the disease refractory to corticosteroids or immunosuppressive drugs?
→ Please indicate: ☐ corticosteroids ☐ immunosuppressive drugs
Please provide the name of drug tried: _____

Behcet's Uveitis
☐ Yes ☐ No Is the disease refractory?

Chronic Cutaneous/Pulmonary sarcoidosis
☐ Yes ☐ No Has the patient remained symptomatic despite treatment with steroids?
→ Please provide the daily dose of steroids: Dose: _____mg
Please indicate length of therapy: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater
☐ Yes ☐ No Has the patient remained symptomatic despite treatment with immunosuppressants?
→ Please select: ☐ azathioprine ☐ cyclophosphamide ☐ methotrexate ☐ Other, please explain: _____
Please indicate length of therapy: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater

Crohn's Disease
☐ Yes ☐ No Does the patient have a diagnosis of fistulizing Crohn's disease?
→ Please indicate how long the patient has been diagnosed with fistulizing Crohn's disease:
Please select: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater
☐ Yes ☐ No Does the patient have a diagnosis of Crohn's disease?
→ Please indicate the severity of the patient's disease: ☐ mild ☐ moderate ☐ severe
☐ Yes ☐ No Does the patient have a documented diagnosis of active Crohn's disease?
→ Please select all signs/symptoms that apply:
☐ abdominal pain ☐ arthritis ☐ bleeding ☐ diarrhea ☐ internal fistulae ☐ intestinal obstruction
☐ megacolon ☐ perianal disease ☐ spondylitis ☐ weight loss ☐ None of the above
☐ Yes ☐ No Have the Crohn's disease symptoms remained active despite treatment with 6-mercaptopurine, azathioprine, or corticosteroids?
→ Please check all medications that apply: ☐ 6-mercaptopurine ☐ azathioprine
☐ corticosteroids- please identify: ☐ prednisone ☐ hydrocortisone ☐ methylprednisolone ☐ Other: _____
Please indicate the length of the medication trial: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater

Hidradenitis Suppurativa
Please indicate the stage of hidradenitis suppurativa: ☐ Hurley stage I (mild disease) ☐ Hurley stage II (moderate disease)
☐ Hurley stage III (severe disease) ☐ Unknown
☐ Yes ☐ No Has the patient completed a trial of antibiotics?
→ ☐ Yes ☐ No Does the patient have a contraindication to oral antibiotics?
→ ☐ Yes ☐ No Was the treatment with antibiotics ineffective?
→ Please indicate the length of the medication trial: ☐ Less than 1 month ☐ 1 month
☐ 2 months ☐ 3 months (90 days) or greater

Immune Checkpoint Inhibitor- Induced Toxicities
Please indicate therapy used:
☐ CTLA-4
Please select drug: ☐ ipilimumab ☐ Other: _____
☐ PD-1
Please select drug: ☐ nivolumab ☐ pembrolizumab ☐ Other: _____
☐ PD-L1
Please select drug: ☐ atezolizumab ☐ avelumab ☐ durvalumab ☐ Other: _____
☐ Other
Please explain: _____
☐ Yes ☐ No Do the immune checkpoint inhibitor-induced toxicities persist despite discontinuation of immune checkpoint inhibitors that target CTLA-4 or PD-1/PD-L1 (e.g., atezolizumab, ipilimumab, nivolumab, pembrolizumab)?

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G. CLINICAL INFORMATION *(continued)* – Required clinical information must be completed in its entirety for all precertification requests.

Please indicate the toxicity (check all that apply:)

☐ Cardiac Which life-threatening immune checkpoint inhibitor-induced cardiac toxicities does the patient have?
Please select: ☐ arrhythmias ☐ impaired ventricular function ☐ myocarditis ☐ pericarditis

☐ Colitis Please indicate the severity of the immune checkpoint inhibitor-induced colitis: ☐ mild ☐ moderate ☐ severe
Please indicate which of the following symptoms the patient exhibits: ☐ 7 or more stools per day over baseline ☐ ileus ☐ fever ☐ None
☐ Yes ☐ No Has the patient been treated with corticosteroids?
→ Please indicate the corticosteroid name: _____
☐ Yes ☐ No Did the patient show improvement after 48 hours of corticosteroids?

☐ Elevated serum creatinine/acute renal failure
Please indicate the severity of the disease:
☐ Severe (creatinine greater than 3 times baseline or greater than 4 mg/dL)
☐ Life-threatening (creatinine greater than 6 times baseline; dialysis indicated)
☐ None of the above
☐ Yes ☐ No Has the patient been treated with corticosteroids?
→ Please indicate the name and length of therapy: Name: _____ Length: ☐ Less than 1 week ☐ 1 week or greater
☐ Yes ☐ No Did the creatinine level remain greater than 2 to 3 times above baseline after 1 week of treatment with corticosteroids?

☐ Inflammatory arthritis
☐ Yes ☐ No Does the patient have refractory or severe disease? ☐ refractory disease ☐ severe disease
☐ Yes ☐ No Is the patient responding to corticosteroids or anti-inflammatory agents? ☐ anti-inflammatory agents ☐ corticosteroids

☐ Pneumonitis
Please indicate the severity of the disease: ☐ mild ☐ moderate ☐ severe
☐ Yes ☐ No Has the patient been treated with corticosteroids for pneumonitis?
→ Please indicate the corticosteroid name: _____
☐ Yes ☐ No Did the patient show improvement after 48 hours of corticosteroids?

Juvenile Idiopathic Arthritis (Juvenile Rheumatoid Arthritis)
Please indicate the severity of the patient's disease: ☐ mild ☐ moderate ☐ severe
☐ Yes ☐ No Is there evidence that the disease is active?
☐ Yes ☐ No Does the patient have clinical documentation of polyarticular juvenile idiopathic arthritis (JRA)?
☐ Yes ☐ No Was treatment with Enbrel (etanercept) ineffective?
→ Please indicate the length of the medication trial: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater
☐ Yes ☐ No Does the patient have a documented intolerance to Enbrel (etanercept)?
☐ Yes ☐ No Does the patient have a documented contraindication to Enbrel (etanercept)?

Noninfectious Uveitis
☐ Yes ☐ No Was the treatment with corticosteroids ineffective?
→ Please indicate the corticosteroid name: _____
Please indicate the length of the medication trial: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater
☐ Yes ☐ No Was the treatment with immunosuppressive drugs (e.g., azathioprine, cyclosporine, or methotrexate) ineffective?
→ Please provide the name: _____
Please indicate the length of the medication trial: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater
☐ Yes ☐ No Does the patient have a documented intolerance to corticosteroids or immunosuppressive drugs?
→ Please indicate the drug(s) the patient has intolerance to: ☐ corticosteroids ☐ immunosuppressive drugs
☐ Yes ☐ No Does the patient have a documented contraindication to corticosteroids or immunosuppressive drugs?
→ Please indicate the drug(s) the patient has contraindication to: ☐ corticosteroids ☐ immunosuppressive drugs

Plaque Psoriasis
Please indicate the severity of the patient's disease: ☐ mild ☐ moderate ☐ severe
☐ Yes ☐ No Is there evidence that the disease is active?
☐ Yes ☐ No Is there clinical documentation of chronic disease?
☐ Yes ☐ No Is the patient a candidate for systemic therapy or phototherapy?
→ Please select: ☐ phototherapy ☐ systemic therapy ☐ phototherapy and systemic therapy
Please provide the patient's Psoriasis Area and Severity Index (PASI) score: _____
Please indicate the percentage of body surface area affected by plaque psoriasis: _____%
☐ Yes ☐ No Does the plaque psoriasis involve sensitive areas? ***If yes***, please select: ☐ hands ☐ feet ☐ face ☐ genitals
☐ Yes ☐ No Was the trial with systemic conventional DMARD(s) (e.g., methotrexate, acetretin, or cyclosporine) ineffective?
→ ☐ Yes ☐ No Was the trial with systemic conventional DMARD(s) not tolerated?
☐ Yes ☐ No Are systemic conventional DMARDs contraindicated?
→ Please select: ☐ acetretin ☐ cyclosporine ☐ methotrexate ☐ mycophenolate ☐ None of the above
Please indicate the length of the medication trial: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater
☐ Yes ☐ No Was the trial with phototherapy ineffective?
→ ☐ Yes ☐ No Was the trial with phototherapy not tolerated?
☐ Yes ☐ No Is phototherapy contraindicated?
→ Please check all that apply: ☐ Psoralens (methoxsalen, trioxsalen) with UVA light (PUVA) ☐ UVB with coal tar or dithranol
☐ UVB (standard or narrow band) ☐ Home UVB ☐ None of the above
Please indicate the length of trial: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater

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G. CLINICAL INFORMATION *(continued)* – Required clinical information must be completed in its entirety for all precertification requests.

Psoriatic Arthritis

☐ Yes ☐ No Is there evidence that the disease is active?
☐ Yes ☐ No Does the patient have **axial** psoriatic arthritis?
→ ☐ Yes ☐ No Was the treatment with 2 or more non-steroidal anti-inflammatory drugs (NSAIDs) ineffective?
→ Please provide the names and length of treatment:
NSAID #1: _____
Please indicate length of treatment: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater
NSAID #2: _____
Please indicate length of treatment: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater
☐ Yes ☐ No Does the patient have **non-axial** psoriatic arthritis?
→ ☐ Yes ☐ No Does the patient have severe disease at presentation, defined as severe disability at onset with erosive disease involving multiple joints?
→ ☐ Yes ☐ No Was the treatment with methotrexate ineffective?
→ ☐ Yes ☐ No Was treatment with methotrexate not tolerated or contraindicated?
→ Please select: ☐ not tolerated ☐ contraindicated
☐ Yes ☐ No Was treatment with another conventional DMARD ineffective?
→ Please select: ☐ cyclophosphamide ☐ cyclosporine ☐ hydroxychloroquine ☐ leflunomide ☐ sulfasalazine ☐ Other, please explain: _____
Please indicate length of treatment:
☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater
→ Indicate length of therapy: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater

Pyoderma Gangrenosum

☐ Yes ☐ No Does the patient have a documented diagnosis of refractory pyoderma gangrenosum?

Reactive Arthritis (Reiter's syndrome) or Inflammatory Bowel Disease Arthritis (Enteropathic Arthritis)

Please select which applies to the patient: ☐ reactive arthritis (Reiter's syndrome) ☐ inflammatory bowel disease arthritis (enteropathic arthritis)
☐ Yes ☐ No Was the treatment with methotrexate ineffective?
→ ☐ Yes ☐ No Was the treatment with methotrexate not tolerated?
☐ Yes ☐ No Does the patient have a contraindication to methotrexate?
→ Please indicate length of therapy: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater
☐ Yes ☐ No Was the treatment with sulfasalazine ineffective?
→ ☐ Yes ☐ No Was the treatment with sulfasalazine not tolerated?
☐ Yes ☐ No Does the patient have a contraindication to sulfasalazine?
→ Please indicate length of therapy: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater
☐ Yes ☐ No Was the treatment with non-steroidal anti-inflammatory drugs (NSAIDs) ineffective?
→ ☐ Yes ☐ No Was the treatment with non-steroidal anti-inflammatory drugs (NSAIDs) not tolerated?
☐ Yes ☐ No Does the patient have a contraindication to non-steroidal anti-inflammatory drugs (NSAIDs)?
→ Please provide the name: _____
Please indicate length of therapy: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater

Retinal Vasculitis

☐ Yes ☐ No Was treatment with a conventional DMARD ineffective?
→ ☐ Yes ☐ No Was treatment with a conventional DMARD not tolerated or contraindicated? ☐ not tolerated ☐ contraindicated

Rheumatoid Arthritis

Please indicate the severity of the patient's rheumatoid arthritis: ☐ mild ☐ moderate ☐ severe
☐ Yes ☐ No Is there evidence that the disease is active?
☐ Yes ☐ No Is the patient a NY Medicare Advantage member?
→ ☐ Yes ☐ No Was treatment with methotrexate ineffective?
→ ☐ Yes ☐ No Was treatment with methotrexate not tolerated or contraindicated? ☐ not tolerated ☐ contraindicated
→ ☐ Yes ☐ No Was treatment with another conventional DMARD (other than methotrexate) ineffective?
→ Please select: ☐ azathioprine ☐ hydroxychloroquine ☐ leflunomide ☐ sulfasalazine
Please indicate length of treatment: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater
→ Please indicate length of the methotrexate therapy: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater
→ ☐ Yes ☐ No Will the patient be using Inflectra (infliximab-dyyb) in combination with methotrexate?
→ ☐ Yes ☐ No Was the treatment with methotrexate not tolerated?
☐ Yes ☐ No Does the patient have a contraindication to methotrexate?
→ ☐ Yes ☐ No Has the patient had a minimum of at least a 3-month trial of methotrexate?
→ ☐ Yes ☐ No Was the treatment with methotrexate not tolerated?
☐ Yes ☐ No Does the patient have a contraindication to methotrexate?

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G. CLINICAL INFORMATION *(continued)* – Required clinical information must be completed in its entirety for all precertification requests.

Sarcoidosis

☐ Yes ☐ No Is the disease refractory to corticosteroids?

Ulcerative Colitis

☐ Yes ☐ No Is the patient hospitalized with active fulminant ulcerative colitis?

→ Please indicate the severity of the patient's ulcerative colitis: ☐ mild ☐ moderate ☐ severe

☐ Yes ☐ No Is there evidence that the disease is active?

☐ Yes ☐ No Is the patient refractory to immunosuppression with corticosteroids (e.g., hydrocortisone, methylprednisolone, prednisone)?

→ ☐ Yes ☐ No Does the patient require continuous immunosuppression with corticosteroids (e.g., hydrocortisone, methylprednisolone, prednisone)?

→ Name and dose: Name: _____ Dose: _____

Please indicate the route: ☐ Oral ☐ IV

Length of time on therapy: ☐ Less than 10 days ☐ 10 to 29 days ☐ 30 days or greater

→ Name and dose: Name: _____ Dose: _____

Please indicate the route: ☐ Oral ☐ IV

Length of time on therapy: ☐ Less than 10 days ☐ 10 to 29 days ☐ 30 days or greater

☐ Yes ☐ No Was treatment with immunosuppressant agent (e.g., azathioprine, 6-mercaptopurine) ineffective?

→ ☐ Yes ☐ No Was treatment with immunosuppressant agent (e.g., azathioprine, 6-mercaptopurine) not tolerated or contraindicated?

→ Please select: ☐ not tolerated ☐ contraindicated

→ Please select: ☐ 6-mercaptopurine ☐ azathioprine ☐ cyclosporine

Please indicate length of treatment: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater

☐ Yes ☐ No Was treatment with 5-aminosalicylic acid agents (e.g., balsalazide, mesalamine, sulfasalazine) ineffective?

→ ☐ Yes ☐ No Was treatment with 5-aminosalicylic acid agents (e.g., balsalazide, mesalamine, sulfasalazine) not tolerated or contraindicated?

→ Please select: ☐ not tolerated ☐ contraindicated

→ Please select: ☐ Colazal (balsalazide) ☐ Ariso, Asacal, Delzicol, Lialda, Pentasa, Rowasa, Canasa (mesalamine)
☐ Azulfidine (sulfasalazine) ☐ Other, please explain: _____

Please indicate length of treatment: ☐ Less than 1 month ☐ 1 month ☐ 2 months ☐ 3 months or greater

→ Please select the symptoms the patient exhibit: ☐ more than 10 stools per day ☐ continuous bleeding ☐ abdominal pain
☐ distension ☐ acute, severe toxic symptoms, including fever and anorexia

For Continuation of Therapy (clinical documentation required for all requests):

Please indicate the length of time on Inflectra (infliximab-dyyb): _____

☐ Yes ☐ No Is this continuation request a result of the patient receiving samples of Inflectra (infliximab-dyyb)?

☐ Yes ☐ No Will Inflectra (infliximab-dyyb) be used concomitantly with apremilast, tofacitinib, or other biologic DMARDs (e.g., adalimumab, certolizumab)?

☐ Yes ☐ No Is there clinical documentation supporting disease stability?

☐ Yes ☐ No Is there clinical documentation supporting disease improvement?

☐ Yes ☐ No Does the patient have any risk factors for TB?

→ ☐ Yes ☐ No Has the patient had a TB test within the past year?

→ (check all that apply): ☐ PPD test ☐ interferon-gamma assay (IGRA) ☐ chest x-ray

Please enter the results of the TB test: ☐ positive ☐ negative ☐ unknown

☐ Yes ☐ No Has the patient received Inflectra (infliximab-dyyb) within the past 6 months?

→ ☐ Yes ☐ No Does the patient have a documented severe and/or potentially life threatening adverse event that occurred during or following the previous infusion?

→ ☐ Yes ☐ No Could the adverse reaction be managed through pre-medication in the home or office setting?

For Crohn's disease, Juvenile idiopathic arthritis, Plaque psoriasis, Rheumatoid arthritis, Ulcerative colitis only:

Please indicate the severity of the disease at baseline (pretreatment with Inflectra (infliximab-dyyb)): ☐ mild ☐ moderate ☐ severe

H. ACKNOWLEDGEMENT

Request Completed 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.

The plan may request additional information or clarification, if needed, to evaluate requests.