

GEORGIA MEDICAID FEE-FOR-SERVICE BIOLOGIC IMMUNOMODULATORS PA SUMMARY

Preferred	Non-Preferred
Adbry (tralokinumab) Arcalyst (rilonacept) Dupixent (dupilumab) Enbrel (etanercept) Fasenra Pen (benralizumab autoinjector) Humira (adalimumab) Ilaris (canakinumab) Kevzara (sarilumab) Nucala Pen (mepolizumab autoinjector) Otezla (apremilast) Rinvoq (upadacitinib) Taltz (ixekizumab) Xeljanz (tofacitinib tablets and oral solution) Xeljanz XR (tofacitinib extended-release) Xolair Pen (omalizumab autoinjector) Siliq (Simposotyk) Stelars Skyriz Tezsp Tremf	nra Subcutaneous (tocilizumab) vita (adalimumab-atto) elx (bimekizumab-bkzx) qo (abrocitinib) ta (certolizumab) tyx (secukinumab) yng (satralizumab-mwge) io Pen (vedolizumab peninjector) et (anakinra) to (ritlecitinib) tiant (baricitinib) to (mirikizumab-mrkz) tia Subcutaneous (abatacept) tock (belumosudil) (brodalumab) tu (deucravacitinib) ta (ustekinumab) ti (risankizumab) tire Pen (tezepelumab-ekko autoinjector) fya (guselkumab) oity (etrasimod) entra (infliximab-dyyb)

The drug names above include all available oral or subcutaneous formulations under the same primary name.

LENGTH OF AUTHORIZATION: Varies

NOTES:

- All preferred and non-preferred products require prior authorization. Intravenous (IV) formulations of the biologic immunomodulators are not covered under Pharmacy Services.
- The criteria details below are for the outpatient pharmacy program. If a medication is being administered in a physician's office or clinic, then the medication must be billed through the DCH physician services program and not the outpatient pharmacy program. Information regarding the physician services program is located at www.mmis.georgia.gov.

PA CRITERIA:

Actemra Subcutaneous

❖ Approvable for members 2 years of age or older with a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) who have tried methotrexate and two of the following, Rinvoq, Enbrel and Humira for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions or



- intolerable side effects with methotrexate and two of the following, Rinvoq, Enbrel and Humira.
- ❖ Approvable for members 2 years of age or older with a diagnosis of moderately to severely active systemic juvenile idiopathic arthritis (SJIA) who have experienced an inadequate response, allergies, contraindications, drug-drug interactions or intolerable side effects with nonsteroidal anti-inflammatories (NSAIDs) and glucocorticosteroids, or members with severe disease who have experienced an inadequate response, allergy, contraindication, drug-drug interaction or intolerable side effect with Ilaris.
- ❖ Approvable for members 18 years of age or older with a diagnosis of moderately to severely active rheumatoid arthritis (RA) who have tried methotrexate, alone or in combination with another disease modifying antirheumatic drug (DMARD), and two of the following, Xeljanz, Kevzara, Rinvoq, Enbrel and Humira, for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions or intolerable side effects with methotrexate and two of the following: Xeljanz, Kevzara, Rinvoq, Enbrel and Humira.
- Approvable for members 18 years of age or older with a diagnosis of giant cell (temporal) arteritis (GCA) when used in combination with a tapering course of glucocorticoid.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active systemic sclerosis-associated interstitial lung disease (SSc-ILD) who have experiences an inadequate response, allergies, contraindications, drug-drug interactions, or intolerable side effects with mycophenolate mofetil and cyclophosphamide or azathioprine.

Adbry

❖ Approvable for members 12 years of age or older with a diagnosis of moderate to severe atopic dermatitis (AD, eczema) with ≥10% of body surface area involvement who have tried medium to very high potency topical corticosteroids and topical pimecrolimus (Elidel) or topical tacrolimus (Protopic) and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions or intolerable side effects with topical corticosteroids and topical pimecrolimus (Elidel) or topical tacrolimus (Protopic).

<u>Amjevita</u>

❖ Prescriber must submit a written letter of medical necessity stating the reasons the preferred product, Humira, is not appropriate for the member as well as the member must meet the criteria for Humira.

Arcalyst

- ❖ Approvable for members 12 years of age or older with a diagnosis of cryopyrin-associated periodic syndromes (CAPS, including familial cold auto-inflammatory syndrome [FCAS] and Muckle-Wells syndrome [MWS]).
- Approvable for members 10 kg or older with a diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA).
- Approvable for members 12 years of age or older with a diagnosis of recurrent pericarditis (RP) who have experienced an inadequate response, allergies, contraindications, drug-drug interactions, or intolerable side effects with combination therapy with colchicine and nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticosteroids and/or aspirin.

Bimzelx

❖ Approvable for members 18 years of age or older with a diagnosis of moderate to severe plaque psoriasis (PsO) with ≥10% of body surface area involvement who have tried



- phototherapy as well as Enbrel or Humira and Taltz for 3 months each and failed to achieve an adequate response, or who are unable to tolerate or try phototherapy due to logistical issues and who have allergies, contraindications, drug-drug interactions or intolerable side effects with Enbrel or Humira and Taltz.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active psoriatic arthritis (PsA) who have tried two of the following, Otezla, Rinvoq, Xeljanz, Enbrel, Humira and Taltz, for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with two of the following: Otezla, Rinvoq, Xeljanz, Enbrel, Humira and Taltz.
- Approvable for members 18 years of age or older with a diagnosis of active ankylosing spondylitis (AS) who have tried Enbrel or Humira and Taltz for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with Enbrel or Humira and Taltz.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) who have objective signs of inflammation confirmed by C-reactive protein (CRP) levels above the upper limit of normal (ULN) or sacroiliitis on magnetic resonance imaging (MRI) and who have tried at least two nonsteroidal antiinflammatory drugs (NSAIDs) at maximally-tolerated doses for at least 4 weeks and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions or intolerable side effects with NSAIDs.

<u>Cibingo</u>

- ❖ Approvable for members 12 years of age or older with a diagnosis of refractory moderate atopic dermatitis (AD, eczema) with ≥10% of body surface area involvement who have tried medium to very high potency topical corticosteroids and three of the following topical therapies (1) crisaborole (Eucrisa), (2) ruxolitinib (Opzelura) and (3) pimecrolimus (Elidel) or tacrolimus (Protopic) and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions or intolerable side effects with topical corticosteroids and three of the following topical therapies (1) crisaborole (Eucrisa), (2) ruxolitinib (Opzelura) and (3) pimecrolimus (Elidel) or tacrolimus (Protopic). In addition, members must have tried and failed to achieve an adequate response, or have allergies, contraindications, drug-drug interactions or intolerable side effects with Adbry, Dupixent and Rinvoq.
- ❖ Approvable for members 12 years of age or older with a diagnosis of refractory severe atopic dermatitis (AD, eczema) with ≥10% of body surface area involvement who have tried medium to very high potency topical corticosteroids and topical tacrolimus (Protopic) and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions or intolerable side effects with topical corticosteroids, topical tacrolimus (Protopic). In addition, members must have tried and failed to achieve an adequate response, or have allergies, contraindications, drug-drug interactions or intolerable side effects with Adbry, Dupixent and Rinvoq.

Cimzia

- ❖ Approvable for members 18 years of age or older with a diagnosis of moderately to severely active Crohn's disease (CD) who have tried Humira and Rinvoq for 3 months and failed to achieve an adequate response, or who have an allergy, contraindication, drug-drug interaction or intolerable side effect with Humira and Rinvoq.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active ankylosing spondylitis (AS) who have tried two of the following, Rinvoq, Taltz, Enbrel and Humira for



- 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with two of the following, Rinvoq, Taltz, Enbrel and Humira.
- ❖ Approvable for members 18 years of age or older with a diagnosis of moderately to severely active rheumatoid arthritis (RA) who have tried two of the following, Xeljanz, Kevzara, Rinvoq, Enbrel and Humira, for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions or intolerable side effects with two of the following, Xeljanz, Kevzara, Rinvoq, Enbrel and Humira.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active psoriatic arthritis (PsA) who have tried three of the following, Otezla, Xeljanz, Rinvoq, Taltz, Enbrel and Humira, for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with three of the following: Otezla, Xeljanz, Rinvoq, Taltz, Enbrel and Humira.
- ❖ Approvable for members 18 years of age or older with a diagnosis of moderate to severe plaque psoriasis (PsO) with ≥10% of body surface area involvement who have tried phototherapy and three of the following, Enbrel, Humira, Otezla and Taltz, for 3 months each and failed to achieve an adequate response, or who are unable to tolerate or try phototherapy due to logistical issues and who have allergies, contraindications, drug-drug interactions or intolerable side effects with three of the following: Enbrel, Humira, Otezla and Taltz.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) who have objective signs of inflammation confirmed by C-reactive protein (CRP) levels above the upper limit of normal (ULN) or sacroiliitis on magnetic resonance imaging (MRI) and who have tried at least two nonsteroidal antiinflammatory drugs (NSAIDs) at maximally-tolerated doses for at least 4 weeks as well as tried Rinvoq and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions or intolerable side effects to NSAIDs and Rinvoq.

Cosentyx

- ❖ Approvable for members 6 years of age or older with a diagnosis of moderate to severe plaque psoriasis (PsO) with ≥10% of body surface area involvement who have tried phototherapy and three of the following, Enbrel, Humira, Otezla and Taltz, for 3 months each and failed to achieve an adequate response, or who are unable to tolerate or try phototherapy due to logistical issues and who have allergies, contraindications, drug-drug interactions, or intolerable side effects with three of the following: Enbrel, Humira, Otezla and Taltz.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active ankylosing spondylitis (AS) who have tried three of the following, Rinvoq, Taltz, Enbrel and Humira for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with three of the following, Rinvoq, Taltz, Enbrel and Humira.
- ❖ Approvable for members 2 to 17 years of age with a diagnosis of active psoriatic arthritis (PsA) who have tried at least two preferred disease modifying antirheumatic drugs (DMARDs) and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions or intolerable side effects with at least two preferred DMARDs.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active psoriatic arthritis (PsA) who have tried three of the following, Otezla, Xeljanz, Rinvoq, Taltz, Enbrel and Humira, and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions or intolerable side effects with three of the following: Otezla, Xeljanz, Rinvoq, Taltz, Enbrel and Humira.



- ❖ Approvable for members 18 years of age or older with a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) who have objective signs of inflammation confirmed by C-reactive protein (CRP) levels above the upper limit of normal (ULN) or sacroiliitis on magnetic resonance imaging (MRI) and who have tried at least two nonsteroidal anti-inflammatory drugs (NSAIDs) at maximally-tolerated doses for at least 4 weeks as well as tried Rinvoq and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions or intolerable side effects to NSAIDs and Rinvoq.
- Approvable for members 4 years of age or older with a diagnosis of active enthesitis-related arthritis (ERA) who have tried at least two preferred disease modifying antirheumatic drugs (DMARDs) and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions or intolerable side effects with at least two preferred DMARDs.
- ❖ Approvable for members 18 years of age or older with a diagnosis of moderate to severe hidradenitis suppurativa (acne inversa) who have tried and failed to achieve an adequate response with oral antibiotic therapy as well tried Humira for 3 months and failed to achieve an adequate response or have an allergy, contraindication, drug-drug interaction or intolerable side effect with Humira.

Dupixent

- ❖ Approvable for members 6 months of age or older with a diagnosis of moderate to severe atopic dermatitis (AD, eczema) with ≥10% of body surface area involvement who have tried medium to very high potency topical corticosteroids and topical pimecrolimus (Elidel) or topical tacrolimus (Protopic) and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions or intolerable side effects with topical corticosteroids and topical pimecrolimus (Elidel) or topical tacrolimus (Protopic).
- ❖ Approvable for members 6 years of age or older with a diagnosis of moderate to severe asthma of eosinophilic phenotype (eosinophil count ≥150 cells/mcL) who have tried a medium-to-high dose inhaled corticosteroid with a long-acting beta agonist or other non-corticosteroid controller medication and failed to achieve asthma control and when the medication is being added on to the member's current maintenance asthma therapy.
- Approvable for members 6 years of age or older with a diagnosis of moderate to severe asthma who are dependent on an oral corticosteroid and who have tried a high dose inhaled corticosteroid with a long-acting beta agonist or other non-corticosteroid controller medication and failed to achieve asthma control and when the medication is being added on to the member's current maintenance asthma therapy.
- ❖ Approvable for members 18 years of age or older with a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) who have tried oral corticosteroid therapy and failed to achieve an adequate response, or the member is not a candidate for oral corticosteroid therapy and who are currently using an intranasal corticosteroid therapy and failed to achieve an adequate response.
- Approvable for members 1 year of age or older who weigh 15 kg or more with a diagnosis of eosinophilic esophagitis (EoE) and whose intraepithelial eosinophils per high-power field (eos/hpf) level is ≥15 and who have tried and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions or intolerable side effects with proton pump inhibitors (PPIs).
- ❖ Approvable for members 18 years of age or older with a diagnosis of prurigo nodularis (PN) who has 20 or more nodular lesions who have tried phototherapy and failed to achieve an adequate response or is unable to tolerate or try phototherapy due to logistical issues.



Enbrel

- ❖ Approvable for members 18 years of age or older with a diagnosis of moderately to severely active rheumatoid arthritis (RA) when the member has tried methotrexate alone or in combination with another DMARD for 3 months and failed to achieve an adequate response.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active psoriatic arthritis (PsA) when the member has tried a generic DMARD and failed to achieve an adequate response.
- Approvable for members 18 years of age or older with a diagnosis of active ankylosing spondylitis (AS) when the member has tried two nonsteroidal anti-inflammatory drugs (NSAIDs) and failed to achieve an adequate response OR when NSAIDs are contraindicated.
- ❖ Approvable for members 4 years of age or older with a diagnosis of moderate to severe plaque psoriasis (PsO) with ≥10% of body surface area involvement when the member has tried phototherapy for 3 months or who are unable to tolerate or try phototherapy due to logistical issues as well as has tried topical and systemic therapy and failed to achieve an adequate response.
- ❖ Approvable for members 2 years of age or older with a diagnosis of moderately to severely active juvenile idiopathic arthritis (JIA)/juvenile rheumatoid arthritis (JRA) when the member has tried methotrexate for 3 months and failed to achieve an adequate response OR when methotrexate is contraindicated.
- ❖ Approvable for members 2 years of age or older with a diagnosis of active juvenile psoriatic arthritis (JPsA) when the member has tried a generic DMARD and failed to achieve an adequate response.

Enspryng

❖ Approvable for members 18 years of age or older with a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive and who have a core clinical characteristic of NMOSD and have experienced at least one relapse in the last 12 months or two relapses in the last 2 years on current therapy.

Entyvio Pen

- Approvable for members 18 years of age or older with a diagnosis of moderately to severely active Crohn's disease (CD) who have tried Humira and Rinvoq for 3 months and failed to achieve an adequate response, or who have an allergy, contraindication, drug-drug interaction, or intolerable side effect with Humira and Rinvoq.
- Approvable for members 18 years of age or older with a diagnosis of moderately to severely active ulcerative colitis (UC) who have tried Humira and Rinvoq for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with Humira and Rinvoq.
- ❖ In addition, members must have received at least 2 intravenous doses of Entyvio.

Fasenra Pen

❖ Approvable for members 6 years of age or older with a diagnosis of severe asthma of eosinophilic phenotype (eosinophil count ≥150 cells/mcL) who have tried a high dose inhaled corticosteroid with a long-acting beta agonist or other non-corticosteroid controller medication and/or systemic glucocorticoids for 50% or more of the year and failed to achieve asthma control and when the medication is being added on to the member's current maintenance asthma therapy.



Humira

- ❖ Approvable for members 18 years of age or older with a diagnosis of moderately to severely active rheumatoid arthritis (RA) when the member has tried methotrexate alone or in combination with another DMARD for 3 months and failed to achieve an adequate response.
- Approvable for members 6 years of age or older with a diagnosis of moderately to severely active Crohn's disease (CD) when the member has tried conventional therapy (corticosteroids, immunosuppressants, sulfasalazine, mesalamine) and failed to achieve an adequate response.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active psoriatic arthritis (PsA) when the member has tried a generic DMARD and failed to achieve an adequate response.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active ankylosing spondylitis (AS) when the member has tried two NSAIDs and failed to achieve an adequate response OR when NSAIDs are contraindicated.
- ❖ Approvable for members 18 years of age or older with a diagnosis of moderate to severe plaque psoriasis (PsO) with ≥10% of body surface area involvement when the member has tried phototherapy for 3 months or who are unable to tolerate or try phototherapy due to logistical issues as well as has tried topical and systemic therapy and failed to achieve an adequate response.
- ❖ Approvable for members 2 years of age or older with a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis/juvenile rheumatoid arthritis (JIA/JRA) when the member has tried methotrexate for 3 months and failed to achieve an adequate response OR when methotrexate is contraindicated.
- Approvable for members 5 years of age or older with a diagnosis of moderately to severely active ulcerative colitis (UC) when the member has tried oral or intravenous corticosteroids AND at least one of the following: 6-mercaptopurine or azathioprine and failed to achieve an adequate response.
- Approvable for members 12 years of age or older with a diagnosis of moderate to severe hidradenitis suppurativa (acne inversa) who have tried oral antibiotic therapy and failed to achieve an adequate response.
- Approvable for members 2 years of age or older with a diagnosis of non-infectious intermediate uveitis, posterior uveitis or panuveitis when the member has tried antimetabolite (e.g., azathioprine, methotrexate, mycophenolate mofetil) or calcineurin inhibitor therapy (e.g., cyclosporine, tacrolimus) and failed to achieve an adequate response.

<u>Ilaris</u>

- ❖ Approvable for members 4 years of age or older with a diagnosis of cryopyrin-associated periodic syndromes (CAPS; includes familial cold auto-inflammatory syndrome [FCAS] and Muckle-Wells syndrome [MWS]).
- Approvable for members 2 years of age or older with a diagnosis of moderately active systemic juvenile idiopathic arthritis (SJIA) who have experienced inadequate response, allergies, contraindications, drug-drug interactions, or intolerable side effects with NSAIDs and glucocorticosteroids.
- ❖ Approvable for members 2 years of age or older with a diagnosis of severely active SJIA.
- ❖ Approvable for members 2 years of age or older with a diagnosis of tumor necrosis factor receptor (TNF) associated periodic syndrome (TRAPS), hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD) or familial Mediterranean fever (FMF).



- ❖ Approvable for members 2 years of age or older with a diagnosis of active Still's disease (SD), including adult-onset Still's disease (AOSD), who have tried a glucocorticoid (i.e., prednisone) for 2 months and failed to achieve an adequate response or was unable to lower dose.
- ❖ Approvable for members 18 years of age or older with a diagnosis of gout who have experienced 3 or more gout flares in the previous year who have experienced inadequate response, allergies, contraindications, drug-drug interactions or intolerable side effects with NSAIDs and colchicine, and in whom repeated courses of corticosteroids are not appropriate.

Kevzara

- Approvable for members who weigh 63 kg or more with a diagnosis of moderately to severely active rheumatoid arthritis (RA) who have tried one of the following, Xeljanz, Enbrel or Humira, for 3 months each and failed to achieve an adequate response, or who have an allergy, contraindication, drug-drug interaction or intolerable side effect with one of the following: Xeljanz, Enbrel or Humira.
- ❖ Approvable for members who weigh 63 kg or more with a diagnosis of polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or cannot tolerate corticosteroid taper.
- ❖ Approvable for members who weigh 63 kg or more with a diagnosis of active polyarticular juvenile idiopathic arthritis (PJIA) who have tried methotrexate for 3 months and failed to achieve an adequate response or is methotrexate contraindicated.

Kineret

- ❖ Approvable for members 18 years of age or older with a diagnosis of moderately to severely active rheumatoid arthritis (RA) who have tried two of the following, Xeljanz, Kevzara, Rinvoq, Enbrel and Humira, for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions or intolerable side effects with two of the following: Xeljanz, Kevzara, Rinvoq, Enbrel and Humira.
- ❖ Approvable for members with a diagnosis of neonatal-onset multisystem inflammatory disease (NOMID) associated with cryopyrin-associated periodic syndromes (CAPS).
- ❖ Approvable for members with a diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA).

Litfulo

- ❖ Approvable for members 12 to 17 years of age or older with a diagnosis of severe alopecia areata for at least 6 months with 50% or more scalp hair loss.
- ❖ Approvable for members 18 years of age or older with a diagnosis of severe alopecia areata for at least 6 months with 50% or more scalp hair loss when the member has failed to achieve an adequate response with Olumiant or prescriber provides valid clinical rationale of why Olumiant is not appropriate for the member.

Nucala Pen

❖ Approvable for members 6 years of age or older with a diagnosis of severe asthma of eosinophilic phenotype (eosinophil count ≥150 cells/mcL) who have tried a high dose inhaled corticosteroid with a long-acting beta agonist or other non-corticosteroid controller medication and/or systemic glucocorticoids for 50% or more of the year and failed to achieve asthma control and when the medication is being added on to the member's current maintenance asthma therapy.



- ❖ Approvable for members 18 years of age or older with a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) who have tried glucocorticoid (e.g., prednisone, methylprednisolone, prednisolone) in combination with an immunosuppressant (e.g., cyclophosphamide, azathioprine, methotrexate, leflunomide) for at least 6 months and failed to achieve an adequate response or who have allergies, contraindications, drug-drug interactions or intolerable side effects to glucocorticoids and immunosuppressants.
- ❖ Approvable for member 12 years of age or older with a diagnosis of hypereosinophilic syndrome (HES) for at least 6 months without an identifiable non-hematologic secondary cause who have an eosinophil count ≥1000 cells/mcL and who have been on stable HES therapy (e.g., corticosteroid, immunosuppressive and/or cytotoxic therapy) and have experienced 2 or more flares in the previous 12 months.
- ❖ Approvable for members 18 years of age or older with a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) who have tried oral corticosteroid therapy and failed to achieve an adequate response, or the member is not a candidate for oral corticosteroid therapy and who are currently using an intranasal corticosteroid therapy and failed to achieve an adequate response.

Olumiant

- ❖ Approvable for members 18 years of age or older with a diagnosis of moderately to severely active rheumatoid arthritis (RA) who have tried methotrexate, alone or in combination with another DMARD, as well as Xeljanz, Kevzara, Rinvoq, Enbrel and Humira for 3 months each and failed to achieve an adequate response or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with Xeljanz, Kevzara, Rinvoq, Enbrel and Humira.
- ❖ Approvable for members 18 years of age or older with a diagnosis of severe alopecia areata for at least 6 months with 50% or more scalp hair loss.

Omvoh

Approvable for members with a diagnosis of moderately to severely active ulcerative colitis (UC) who have been approved for or have received intravenous induction therapy in a clinic setting.

Orencia Subcutaneous

- Approvable for members 18 years of age or older with a diagnosis of moderately to severely active rheumatoid arthritis (RA) who have tried methotrexate, alone or in combination with another disease modifying antirheumatic drug (DMARD), and two of the following, Xeljanz, Kevzara, Rinvoq, Enbrel and Humira, for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions or intolerable side effects with two of the following: Xeljanz, Kevzara, Rinvoq, Enbrel and Humira.
- Approvable for members 2 to 17 years of age or with a diagnosis of active psoriatic arthritis (PsA) who have tried Enbrel and Rinvoq for 3 months and failed to achieve an adequate response, or who has an allergy, contraindication, drug-drug interaction, or intolerable side effect with Enbrel and Rinvoq.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active psoriatic arthritis (PsA) who have tried three of the following, Otezla, Xeljanz, Rinvoq, Taltz, Enbrel and Humira, for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with three of the following: Otezla, Xeljanz, Rinvoq, Taltz, Enbrel and Humira.



❖ Approvable for members 2 years of age or older with a diagnosis of moderately to severely active juvenile idiopathic arthritis/juvenile rheumatoid arthritis (JIA/JRA) who have tried two of the following, Rinvoq, Enbrel and Humira for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with two of the following, Rinvoq, Enbrel and Humira.

<u>Otezla</u>

- Approvable for members 18 years of age or older with a diagnosis of active psoriatic arthritis (PsA) who have tried one generic DMARD and failed to achieve an adequate response.
- ❖ Approvable for members 18 years of age or older with plaque psoriasis (PsO) with ≥10% of body surface area involvement who have tried phototherapy for 3 months or who are unable to tolerate or try phototherapy due to logistical issues as well as have tried topical and systemic therapy and failed to achieve an adequate response.
- ❖ Approvable for members 18 years of age or older with a diagnosis of at least 2 active oral ulcers associated with Behcet's disease and when other causes of the oral ulcers have been ruled out.

Rezurock

❖ Approvable for members 12 years of age or older with a diagnosis of chronic graft-versushost disease (chronic GVHD) who are previous recipient of an allogeneic hematopoietic stem cell transplant and have experienced inadequate response, allergies, contraindications, drugdrug interactions, or intolerable side effects with at least 2 prior lines of systemic therapy.

Rinvoq

- Approvable for members 18 years of age or older with a diagnosis of moderately to severely active rheumatoid arthritis (RA) who have tried Enbrel or Humira for 3 months and failed to achieve an adequate response or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with Enbrel or Humira.
- Approvable for members 2 years of age or older with a diagnosis of active psoriatic arthritis (PsA) who have tried Enbrel or Humira for 3 months and failed to achieve an adequate response or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with Enbrel or Humira.
- ❖ Approvable for members 12 years of age or older with a diagnosis of refractory, moderate atopic dermatitis (AD, eczema) with ≥10% of body surface area involvement who have tried and failed to achieve an adequate response, or who have allergies, contraindications, drugdrug interactions or intolerable side effects with any systemic product for atopic dermatitis (e.g., DMARD therapy or another systemic biologic agent).
- Approvable for members 18 years of age or older with a diagnosis of moderately to severely active ulcerative colitis (UC) who have tried Humira for 3 months and failed to achieve an adequate response, or who have an allergy, contraindication, drug-drug interaction or intolerable side effect with Humira.
- Approvable for members 18 years of age or older with a diagnosis of moderately to severely active Crohn's disease (CD) who have tried Humira for 3 months and failed to achieve an adequate response or who have an allergy, contraindication, drug-drug interaction or intolerable side effect with Humira.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active ankylosing spondylitis (AS) who have tried Enbrel or Humira for 3 months and failed to achieve an



- adequate response, or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with Enbrel or Humira.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) who have objective signs of inflammation confirmed by C-reactive protein (CRP) levels above the upper limit of normal (ULN) or sacroiliitis on magnetic resonance imaging (MRI) and who have tried nonsteroidal antiinflammatory drugs (NSAIDs) at maximally-tolerated doses for at least 4 weeks and failed to achieve an adequate response, or who have an allergy, contraindication, drug-drug interaction or intolerable side effect to NSAIDs.
- Approvable for members 2 years of age or older with a diagnosis of active polyarticular juvenile idiopathic arthritis (PJIA) who have tried Enbrel or Humira for 3 months and failed to achieve an adequate response or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with Enbrel or Humira.

<u>Siliq</u>

❖ Approvable for members 18 years of age or older with a diagnosis of moderate to severe plaque psoriasis (PsO) with ≥10% of body surface area involvement who have tried phototherapy and three of the following, Otezla, Taltz, Enbrel and Humira, for 3 months each and failed to achieve an adequate response, or who are unable to tolerate or try phototherapy due to logistical issues and who have allergies, contraindications, drug-drug interactions, or intolerable side effects with three of the following: Otezla, Taltz, Enbrel and Humira.

Simponi

- Approvable for members 18 years of age or older with a diagnosis of moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate who have tried two of the following, Xeljanz, Kevzara, Rinvoq, Enbrel and Humira, for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with methotrexate and two of the following: Xeljanz, Kevzara, Rinvoq, Enbrel and Humira.
- Approvable for members 18 years of age or older with a diagnosis of active ankylosing spondylitis (AS) who have tried two of the following, Rinvoq, Taltz, Enbrel and Humira, for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with Rinvoq, Taltz, Enbrel and Humira.
- ❖ Approvable for members 18 years of age or older with a diagnosis of moderately to severely active ulcerative colitis (UC) who have tried Humira and Rinvoq for 3 months each and failed to achieve an adequate response, or who have an allergy, contraindication, drug-drug interaction, or intolerable side effect with Humira and Rinvoq.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active psoriatic arthritis (PsA) who have tried three of the following, Otezla, Xeljanz, Rinvoq, Taltz, Enbrel and Humira, for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with three of the following: Otezla, Xeljanz, Rinvoq, Taltz, Enbrel and Humira.

Skvrizi

❖ Approvable for members 18 years of age or older with a diagnosis of moderate to severe plaque psoriasis (PsO) with ≥10% of body surface area involvement who have tried phototherapy and three of the following, Enbrel, Humira, Otezla, and Taltz for 3 months each



- and failed to achieve an adequate response, or who are unable to tolerate or try phototherapy due to logistical issues and who have allergies, contraindications, drug-drug interactions, or intolerable side effects with three of the following: Enbrel, Humira, Otezla and Taltz.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active psoriatic arthritis (PsA) who have tried three of the following, Otezla, Xeljanz, Rinvoq, Taltz, Enbrel and Humira, for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with three of the following: Otezla, Xeljanz, Rinvoq, Taltz, Enbrel and Humira.
- Approvable for members 18 years of age or older with a diagnosis of moderately to severely active Crohn's disease (CD) who have tried Humira and Rinvoq for 3 months and failed to achieve an adequate response, or who have an allergy, contraindication, drug-drug interaction, or intolerable side effect with Humira and Rinvoq.
- Approvable for members 18 years of age or older with a diagnosis of moderately to severely active ulcerative colitis (UC) who have tried Humira and Rinvoq for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with Humira and Rinvoq.

Sotyktu

- ❖ Approvable if the following criteria are met:
 - o Member has a diagnosis of moderate to severe plaque psoriasis (PsO); AND
 - o Member is 18 years of age or older; AND
 - o Percentage of member's body surface area involved is 10% or greater; AND
 - Member has tried phototherapy for 3 months and failed to achieve at least a 75% improvement or a clear or almost clear response or member is unable to tolerate or try phototherapy due to logistical issues (financial, travel, etc.); AND
 - Member has tried three of the following, Enbrel, Humira, Otezla, Taltz, for 3 months each and failed to achieve at least a 75% improvement or a clear or almost clear response; *OR*
 - Member has allergies, contraindications, drug-drug interactions or intolerable side effects to three of the following, Enbrel, Humira, Otezla, Taltz.

Stelara

- ❖ Approvable for member 6 years of age or older with a diagnosis of moderate to severe plaque psoriasis (PsO) with ≥10% of body surface area involvement who have tried phototherapy as well as three of the following, Otezla, Taltz, Enbrel and Humira, for 3 months each and failed to achieve an adequate response, or who are unable to tolerate or try phototherapy due to logistical issues and who have allergies, contraindications, drug-drug interactions or intolerable side effects with three of the following: Otezla, Taltz, Enbrel and Humira.
- ❖ Approvable for members 6 to 17 years of age with a diagnosis of active psoriatic arthritis (PsA) who have tried at least two preferred disease modifying antirheumatic drugs (DMARDs) and failed to achieve an adequate response.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active psoriatic arthritis (PsA) who have tried three of the following, Otezla, Xeljanz, Rinvoq, Taltz, Enbrel and Humira, for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with three of the following: Otezla, Xeljanz, Rinvoq, Taltz, Enbrel and Humira.
- ❖ Approvable for members 18 years of age or older with a diagnosis of moderately to severely active Crohn's disease (CD) who have tried Humira and Rinvoq for 3 months and failed to



- achieve an adequate response, or who have an allergy, contraindication, drug-drug interaction, or intolerable side effect with Humira and Rinvoq.
- Approvable for members 18 years of age or older with a diagnosis of moderately to severely active ulcerative colitis (UC) who have tried Humira and Rinvoq for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with Humira and Rinvoq.

Taltz.

- ❖ Approvable for members 6-17 years of age or older with a diagnosis of moderate to severe plaque psoriasis (PsO) with ≥10% of body surface area involvement who have tried phototherapy and Enbrel for 3 months each and failed to achieve an adequate response, or who are unable to tolerate or try phototherapy due to logistical issues and who have an allergy, contraindication, drug-drug interaction, or intolerable side effect with Enbrel.
- ❖ Approvable for members 18 years of age or older with a diagnosis of moderate to severe plaque psoriasis (PsO) with ≥10% of body surface area involvement who have tried phototherapy and Humira for 3 months each and failed to achieve an adequate response, or who are unable to tolerate or try phototherapy due to logistical issues and who have an allergy, contraindication, drug-drug interaction, or intolerable side effect with Humira.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active psoriatic arthritis (PsA) who have tried one of the following, Otezla, Xeljanz, Enbrel or Humira, for 3 months and failed to achieve an adequate response, or who have an allergy, contraindication, drugdrug interaction or intolerable side effect with one of the following: Otezla, Xeljanz, Enbrel or Humira.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active ankylosing spondylitis (AS) who have tried Enbrel or Humira for 3 months and failed to achieve an adequate response, or who have an allergy, contraindication, drug-drug interaction or intolerable side effect with Enbrel or Humira.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) who have objective signs of inflammation confirmed by C-reactive protein (CRP) levels above the upper limit of normal (ULN) or sacroiliitis on magnetic resonance imaging (MRI) and who have tried at least two nonsteroidal antiinflammatory drugs (NSAIDs) at maximally-tolerated doses for at least 4 weeks and failed to achieve an adequate response, or who have an allergy, contraindication, drug-drug interaction or intolerable side effect to NSAIDs.

Tezspire Pen

- ❖ Approvable for members 12 years of age or older with a diagnosis of severe asthma who have tried a high dose inhaled corticosteroid with a long-acting beta agonist or other non-corticosteroid controller medication and/or systemic glucocorticoids for 50% or more of the year and failed to achieve asthma control and who have tried Dupixent, Fasenra and Nucala and failed to achieve an adequate response or who have allergies, contraindications, drugdrug interactions, or intolerable side effects with Dupixent, Fasenra and Nucala
- ❖ Medication must be added on to the member's current maintenance asthma therapy.

Tremfya

❖ Approvable for members 18 years of age or older with a diagnosis of moderate to severe plaque psoriasis (PsO) with \geq 10% of body surface area involvement who have tried phototherapy and three of the following, Enbrel, Otezla, Taltz and Humira for 3 months each



- and failed to achieve an adequate response, or who are unable to tolerate or try phototherapy due to logistical issues and who have an allergy, contraindication, drug-drug interaction, or intolerable side effect with three of the following: Enbrel, Otezla, Humira and Taltz.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active psoriatic arthritis (PsA) who have tried three of the following, Otezla, Xeljanz, Rinvoq, Taltz, Enbrel and Humira, for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with three of the following: Otezla, Xeljanz, Rinvoq, Taltz, Enbrel and Humira.

Velsipity

❖ Approvable for members 18 years of age or older with a diagnosis of moderately to severely active ulcerative colitis (UC) who have tried oral or intravenous corticosteroids and at least one of the following: 6-mercaptopurine or azathioprine as well as Humira and Xeljanz/Xeljanz XR or Rinvoq and Zeposia and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions or intolerable side effects with corticosteroids, 6-mercaptopurine and azathioprine as well as Humira and Xeljanz/Xeljanz XR or Rinvoq and Zeposia.

Xeljanz and Xeljanz XR

- ❖ Approvable for members 18 years of age or older with a diagnosis of moderately to severely active rheumatoid arthritis (RA) who have tried Enbrel or Humira for 3 months and failed to achieve an adequate response or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with Enbrel or Humira.
- ❖ Approvable for members 18 years of age or older with a diagnosis of active psoriatic arthritis (PsA) who have tried Enbrel or Humira for 3 months and failed to achieve an adequate response or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with Enbrel or Humira.
- ❖ Approvable for members 18 years of age or older with a diagnosis of moderately to severely active ulcerative colitis (UC) who have tried oral or intravenous corticosteroids and at least one of the following: 6-mercaptopurine or azathioprine and failed to achieve an adequate response and who have tried Humira for 3 months each and failed to achieve an adequate response, or who have an allergy, contraindication, drug-drug interaction or intolerable side effect with Humira and when the lowest effective dose for the shortest duration needed to achieve/maintain therapeutic response will be used.
- Approvable for members 2 years of age or older with a diagnosis of active polyarticular course juvenile idiopathic arthritis (pcJIA) who have tried Enbrel or Humira for 3 months and failed to achieve an adequate response or who have allergies, contraindications, drugdrug interactions, or intolerable side effects with Enbrel or Humira.
- ❖ Approvable for members 18 years of age or older with a diagnosis of ankylosing spondylitis (AS) who have tried Enbrel or Humira for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with Enbrel and Humira.
- ❖ In addition to meeting the criteria above for Xeljanz XR, prescriber must also submit a written letter of medical necessity stating the reasons Xeljanz (regular-release) is not appropriate for the member.

Xeljanz Oral Solution



- Approvable for members 2 to 12 years of age with a diagnosis of active polyarticular course juvenile idiopathic arthritis (pcJIA) who have tried Enbrel or Humira for 3 months and failed to achieve an adequate response or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with Enbrel or Humira.
- ❖ Approvable for member 13 years of age or older with a diagnosis of active pcJIA who have tried Enbrel or Humira for 3 months and failed to achieve an adequate response or who have allergies, contraindications, drug-drug interactions, or intolerable side effects with Enbrel or Humira and who are unable to swallow solid oral dosage formulations (i.e., tablets) or require dosing that cannot be obtained with the 5 mg tablets.

Xolair Pen

- ❖ Approvable for members 12 years of age or older with a diagnosis of moderate to severe persistent asthma and a positive skin test or in vitro reactivity to a perennial aeroallergen who have a IgE level of ≥30 and ≤700 IU/mL, weigh ≤150 kg and have tried at least 2 high-dose inhaled corticosteroid-based therapies and failed to achieve adequate asthma control and member will continue on an inhaled corticosteroid.
- Approvable for members 12 years of age or older with a diagnosis of IgE-mediated food allergy confirmed by food specific skin prick test (SPT), IgE antibody in vitro test or oral food challenge (OFC) when the requested medication is being used to reduce Type 1 allergic reactions (e.g., nausea, vomiting, cramping, diarrhea, flushing, pruritus, urticaria, swelling of the lips, face or throat, wheezing, lightheadedness, syncope, anaphylaxis) who have a IgE level of ≥30 and ≤1850 IU/mL, weigh ≤150 kg and member will use the requested medication in conjunction with food allergen avoidance.
- ❖ Approvable for members 12 years of age or older with a diagnosis of chronic spontaneous urticaria (CSU; previously referred to as chronic idiopathic urticaria [CIU]) who have tried at least 2 H1 antihistamine-based therapies and failed to achieve adequate symptomatic control and member will continue on an H1 antihistamine.
- ❖ Approvable for members 18 years of age or older with a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) who have bilateral polyps confirmed by endoscopy, are experiencing nasal congestion, have a IgE level of ≥30 and ≤1500 IU/mL, weigh ≤150 kg and have tried at least 2 intranasal corticosteroid-based therapies and failed to achieve an adequate response and member will continue on an intranasal corticosteroid.
- ❖ In addition, member must have received at least 3 doses of Xolair under the guidance of a healthcare provider with no hypersensitivity reactions and member or caregiver must be able to recognize symptoms of and treat anaphylaxis appropriately.

Zymfentra

- Approvable for members 18 years of age or older with a diagnosis of moderately to severely active ulcerative colitis (UC) who have tried Humira and Rinvoq for 3 months each and failed to achieve an adequate response, or who have allergies, contraindications, drug-drug interactions or intolerable side effects with Humira and Rinvoq.
- ❖ Approvable for members 18 years of age or older with a diagnosis of moderately to severely active Crohn's disease (CD) who have tried Humira and Rinvoq for 3 months each and failed to achieve an adequate response or who have an allergies, contraindications, drug-drug interactions or intolerable side effects with Humira and Rinvoq.
- ❖ In addition, member must have received 9 weeks of intravenous induction therapy with infliximab.

EXCEPTIONS:



- Exceptions to these conditions of coverage are considered through the prior authorization process.
- The Prior Authorization process may be initiated by calling **OptumRx at 1-866-525-5827.**

PREFERRED DRUG LIST:

• For online access to the Preferred Drug List (PDL), please go to http://dch.georgia.gov/preferred-drug-lists.

PA AND APPEAL PROCESS:

 For online access to the PA process, please go to <u>www.dch.georgia.gov/prior-authorization-process-and-criteria</u> and click on Prior Authorization (PA) Request Process Guide.

QUANTITY LEVEL LIMITATIONS:

For online access to the current Quantity Level Limits (QLL), please go to
 <u>www.mmis.georgia.gov/portal</u>, highlight Pharmacy and click on <u>Other Documents</u>, then
 select the most recent quarters QLL list.