Kentucky Department for Medicaid Services
Drug Review and Options for Consideration

The following tables list the Agenda items as well as the Options for Consideration that are scheduled to be presented and reviewed at the **May 19, 2022** meeting of the Pharmacy and Therapeutics Advisory Committee.

Clinical Criteria Review	Options for Consideration

Cibinqo™	Non-preferred in the PDL class: *Cytokine and CAM Antagonists*
	
	Length of Authorization: 6 months initial, 1 year renewal
	• Abrocitinib (Cibinqo) is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.
	Criteria for Approval
	• Patient has moderate-to-severe atopic dermatitis (AD) defined by ≥ 1 of the following:
	  ○ Involvement of ≥ 10% of body surface area (BSA); OR
	  ○ Eczema Area and Severity Index (EASI) score of ≥ 16; OR
	  ○ Investigator's Global Assessment (IGA) score of ≥ 3; OR
	  ○ Scoring Atopic Dermatitis (SCORAD) score of ≥ 25; OR
	  ○ Pruritus Numerical Rating Scale (NRS) score of ≥ 4; OR
	  ○ Incapacitation due to AD lesion location (head and neck, palms, soles, or genitalia); AND
	• Prescribed by, or in consultation with, a dermatologist, rheumatologist or other specialist in the treatment of atopic dermatitis; AND
	• Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; AND
	• Patient will NOT receive live vaccines during therapy; AND
	• The medication will NOT be used in combination with other monoclonal antibody biologics; AND
	• Patient is NOT on concomitant antiplatelet therapies during the first 3 months of treatment (Note: excludes the use of low-dose aspirin) AND
	• Patient does NOT have any clinically relevant laboratory abnormalities (e.g., platelet count <150,000/mm3, an absolute lymphocyte count <500/mm3, an absolute neutrophil count <1,000/mm3, or a hemoglobin value <8 g/dL); AND
	• Patient has had a ≥ 3 month trial and failure, contraindication, or intolerance to ≥ 1 agent in each of the following categories:
	  ○ Topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone) unless inappropriate for the location (e.g., face, groin); AND
	  ○ Topical calcineurin inhibitor (i.e., tacrolimus or pimecrolimus); AND
	  ○ Immunosuppressive systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, dupilumab, tralokinumab-ldrm)
	• Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

Clinical Criteria Review	Options for Consideration

	Renewal Criteria
	• Patient has disease response as indicated by improvement in signs and symptoms compared to baseline in ≥ 1 of the following: pruritus, the amount of surface area involvement, EASI, IGA, SCORAD, and/or NRS; AND
	  ○ Patient has achieved clear or almost clear skin defined as achievement of an IGA 0/1 or EASI-75 at week 16; OR
	  ○ Patient has had an inadequate response to standard doses of therapy after an adequate trial of ≥ 12 weeks OR patient experienced a disease flare and will require higher dosing; AND
	  ○ Patient requires an increase in dose, in accordance with prescribing information recommended dosages (e.g., up to 200 mg daily)
	• Patient has NOT experienced a myocardial infarction or stroke; AND
	• Patient has NOT experienced any treatment-restricting adverse effects
	Age Limit: none
	Quantity Limit: 50 mg, 100 mg, and 200 mg: 30 tablets/30 days

Adbry™	Non-preferred in the PDL class: *Immunomodulators, Atopic Dermatitis*
	
	Length of Authorization: 16 weeks initial, 1 year renewal
	• Tralokinumab-ldrm (Adbry) is an interleukin-13 antagonist indicated for the treatment of moderate-to severe atopic dermatitis (AD) in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable
	Criteria for Approval:
	• Patient will not receive live vaccines during therapy; AND
	• Diagnosis of moderate to severe atopic dermatitis with at least 1 of the following:
	  ○ Involvement of at least 10% of body surface area (BSA); OR
	  ○ Eczema Area and Severity Index (EASI) score of 16 or greater; OR
	  ○ Investigator's Global Assessment (IGA) score of 3 or more; OR
	  ○ Scoring Atopic Dermatitis (SCORAD) score of 25 or more; OR
	  ○ Incapacitation due to AD lesion location (i.e., head and neck,
	  ○ palms, soles, or genitalia); AND
	• Prescribed by, or in consultation with, a dermatologist, allergist/immunologist, or other specialist in the treatment of atopic dermatitis; AND
	• Patient has had a trial and failure, contraindication, or intolerance to at least 1 agent from ≥ 2 of the following classes:
	  ○ Prescription strength topical corticosteroids (e.g., mometasone, fluocinolone) unless inappropriate for the location (e.g., face, groin);
	  ○ Topical calcineurin inhibitor (e.g., pimecrolimus or tacrolimus)
	  ○ Topical phosphodiesterase-4 inhibitor (e.g., crisaborole)
	  ○ Topical Janus kinase inhibitor (e.g., ruxolitinib); AND
	  ○ Immunosuppressive systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, dupilumab, tralokinumab-ldrm
	
	Renewal Criteria:
	• Patient must have disease improvement and/or stabilization from baseline; AND
	• Patient has NOT experienced serious treatment-related adverse events
	Age Limit: ≥ 18 years
	Quantity Limit: 4 syringes per 28 days

Tavneos™	Non-preferred in the PDL class: *Immunosuppressants* **Length of Authorization:** 6 months initial, 1 year renewal

Clinical Criteria Review	Options for Consideration

	• Avacopan (Tavneos) is a complement 5a receptor (C5aR) antagonist indicated as an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids.
	Initial Approval Criteria
	• Patient has severe active antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis; AND
	  ○ Patient has autoantibodies for proteinase 3 (PR3) or myeloperoxidase (MPO), as detected using indirect immunofluorescence (IIF) assay or antigen-specific enzyme linked immunosorbent assays (ELISAs); OR
	  ○ Disease is confirmed by tissue biopsy at the site of active disease; AND
	• Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment; AND
	• Physician has assessed disease severity utilizing an objective measure/tool (e.g., Birmingham Vasculitis Activity Score [BVAS]) and patient has a baseline score of ≥ 16 with 1 of the following:
	  ○ Patient has 1 major item; OR
	  ○ Patient has ≥ 3 non-major items; OR
	  ○ Patient has ≥ 2 renal items of proteinuria and hematuria; AND
	• Patient does NOT have an active infection, including clinically important localized infections; AND
	• Patient has failed on ≥ 1 of the following regimens:
	  ○ Patient has failed immunosuppressant therapy (e.g., cyclophosphamide, azathioprine, methotrexate, mycophenolate), unless contraindicated or not tolerated; OR
	  ○ Patient has failed on anti-CD20 monoclonal antibody therapy (e.g., rituximab), unless contraindicated or not tolerated; AND
	• Avacopan (Tavneos) will be used as adjunctive therapy in combination with standard therapy (e.g., corticosteroids, cyclophosphamide, azathioprine, mycophenolate, rituximab).
	Renewal Criteria
	• Disease response from pre-treatment baseline as indicated by the following:
	  ○ Absence of new symptoms; AND
	  ○ Minimal use of glucocorticoids (e.g., < 5 mg of prednisone or equivalent); AND
	  ○ One or more of the following:
	  ▪ Decrease in relapses/flares and/or ANCA levels; OR
	  ▪ Improvement in organ manifestations (e.g., those with pulmonary-renal syndrome should improve in PFTs, proteinuria, creatinine); OR
	  ▪ Remission (defined as a composite scoring index of 0 on the BVAS); AND
	• Patient has NOT experienced any treatment-restricting adverse effects (e.g., hepatoxicity, severe hypersensitivity reactions, serious infections).
	Age Limit: ≥ 18 years
	Quantity Limit: 180 capsules per 30 days

Leqvio®	Non-preferred in the PDL class: *Lipotropics: Other* **Length of Authorization:** 6 months initial; 1 year renewal

Clinical Criteria Review	Options for Consideration

	• Inclisiran, a small interfering RNA (siRNA) directed to PCSK9 (proprotein convertase subtilisin kexin type 9) mRNA, is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C).
	Criteria for Approval
	• Prescribed initially by, or in consultation with a cardiologist, lipid specialist, endocrinologist, vascular medicine, or other applicable specialist; AND
	• Documentation of low-density lipoprotein cholesterol (LDL-C) prior to/without PCSK9 inhibitor therapy; AND
	• Medication is used to reduce the risk of cardiovascular (CV) events (e.g., myocardial infarction, stroke) in a patient with established CV disease; OR
	• Diagnosis of primary hyperlipidemia, including heterozygous and homozygous familial hypercholesterolemia; AND
	  ○ Trial and failure to achieve LDL goal after 3 months of high intensity statin therapy; OR
	  ○ Patient does not tolerate statins (≥ 2 statin trials of any length were unsuccessful due to adverse effects); AND
	  ○ Maximum tolerated doses of lipid-lowering therapies will continue to be used in combination with PCSK9 therapy.
	Renewal Criteria
	• Documentation of most recent LDL-C while on treatment that demonstrate a reduction in LDL-C when compared to the baseline values.
	Age Limit: ≥ 18 years

Vyvgart™	Non PDL class: *Immunomodulators, miscellaneous* **Length of Authorization:** 3 months initial, 1 year renewal • Efgartigimod alfa-fcab (Vyvgart), a neonatal Fc receptor blocker, is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. **Criteria for Approval** • Diagnosis of Myasthenia Gravis (MGFA Class II to IV disease); AND • Patient has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; AND • Patient has a baseline immunoglobulin G (IgG) level of ≥ 6 g/L (600 mg/dL); AND • Patient does NOT have an active infection, including clinically important localized infections; AND • Patient had an inadequate response after a minimum 1-year trial with ≥ 2 immunosuppressive therapies (e.g., corticosteroids plus an immunosuppressant such as azathioprine, cyclosporine, mycophenolate) OR • Patient required chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy; AND • Efgartigimod will NOT be used in combination with other immunomodulatory biologic therapies; AND • Live-attenuated or live vaccines will NOT be administered during treatment; AND • Patient has a thymoma OR patient does not have a thymoma and is ≤ 50 years of age AND has had a thymectomy • Physician has assessed objective signs of neurological weakness and fatiguability on a baseline neurological examination (e.g., including, but not limited to, the Quantitative Myasthenia Gravis [QMG] score); AND

Clinical Criteria Review	Options for Consideration

	• Patient has a baseline MG-Activities of Daily Living (MG-ADL) total score of ≥ 5.
	Renewal Criteria
	• Patient must have disease improvement as indicated by:
	  ○ reduction in MG-ADL total score of ≥ 2-points from baseline that is sustained for ≥ 4-weeks; OR
	  ○ improvement of ≥ 3-points from baseline in the Quantitative Myasthenia Gravis (QMG) total score sustained for ≥ 4-weeks; AND
	• Patient experiences improvement in muscle strength testing with fatigue maneuvers as evidenced on neurologic examination when compared to baseline; AND
	• Patient requires continuous treatment, after an initial beneficial response, due to new or worsening disease activity (Note: a minimum of 50 days must have elapsed from the start of the previous treatment cycle)
	• Patient has NOT experienced any treatment-restricting adverse effects.
	Age Limit: ≥ 18 years
	Quantity Limit: 3 vials per week for 4 doses per 50 days

Besemri™	Non PDL class: *Immunomodulators, miscellaneous*
	
	Length of Authorization: 1 year
	Ropeginterferon alfa-2b-njft (Besremi) is an interferon alfa-2b indicated for the treatment of adults with polycythemia vera.
	Initial Approval Criteria
	• Patient has a confirmed diagnosis of polycythemia vera; AND
	• Patient does NOT have hypersensitivity to other interferons including interferon alfa-2b or any of the product's inactive ingredients; AND
	• Patient does NOT have a history of severe psychiatric disorders (e.g., severe depression, suicidal ideation, suicide attempt(s)); AND
	• Patient does NOT have moderate-to-severe hepatic impairment (e.g., Child-Pugh B or C); AND
	• Patient does NOT have a history of active serious or untreated autoimmune disease; AND
	• Patient is NOT a transplant recipient on immunosuppressive therapy; AND
	• Patient does NOT have stage 4 renal impairment (e.g., eGFR is < 30 mL/min); AND
	• Ropeginterferon alfa-2b-njft must be used as single agent therapy (note: excludes use when transitioning from hydroxyurea); AND
	• Ropeginterferon alfa-2b-njft will NOT be used in combination with any of the following:
	  - myelosuppressive agents;
	  - interferon type products (e.g., alfa-, beta-, gamma- interferon);
	  - narcotics, hypnotics, or sedatives; AND
	• Patient has a documented failure, contraindication, or ineffective response to maximum tolerated doses of hydroxyurea for a minimum 3-month trial; AND
	• Patient will have ophthalmological examinations prior to start and during therapy; AND
	• Patient will have a complete blood count (CBC) at baseline, during titration, and every 3 to 6 months during the maintenance phase; AND
	• Patient will have liver function tests (LFTs) at baseline and during therapy; AND
	• Patient will be monitored for serum triglycerides (TG) at baseline and intermittently during therapy; AND

Clinical Criteria Review	Options for Consideration

	• Females of reproductive potential must have a negative pregnancy test prior to use and use effective contraception during therapy and for a minimum of 8 weeks following the last dose
	
	Renewal Criteria
	• Patient has maintained hematological stability as evidenced by all of the following parameters:
	  • Hematocrit < 45% and no phlebotomy in the preceding 2 months; AND
	  • Platelets ≤ 400 x 109/L; AND
	  • Leukocytes ≤10 x 109/L; AND
	  • Patients who have maintained a complete hematological response or hematological stability after 1 year of treatment, at stable doses, will attempt a dosing interval increase to 4 weeks; AND
	• Patient has NOT experienced any treatment-restricting adverse effects
	Age Limit: ≥ 18 years

Tezspire™	Non-preferred in the PDL class: *Immunomodulators, Asthma*
	
	Length of Authorization: 1 year
	• Tezepelumab-ekko (Tezspire), a thymic stromal lymphopoietin (TSLP) inhibitor, is indicated for the add-on maintenance treatment of adult and pediatric patients aged ≥ 12 years with severe asthma.
	Criteria for Approval:
	• Patient must have a diagnosis of severe asthma; AND
	• Must be used for add-on maintenance treatment in patients regularly receiving BOTH of the following:
	  ○ Medium- to high-dose inhaled corticosteroids; AND
	  ○ An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers); AND
	• Patient must have had, in the previous year, at least 2 exacerbations requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) OR one exacerbation resulting in a hospitalization; AND
	• Baseline measurement of ≥ 1 of the following for assessment of clinical status:
	  ○ Use of systemic corticosteroids; OR
	  ○ Use of inhaled corticosteroids; OR
	  ○ Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition; OR
	  ○ FEV1; AND
	• Must not be used in combination with anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody agents (e.g., benralizumab, omalizumab, mepolizumab, reslizumab, dupilumab); AND
	• Patient does not have an active or untreated helminth infection; AND
	• Will not be administered concurrently with live vaccines; AND
	• Patient has had a trial and failure, contraindication, or intolerance to at least 1preferred agent
	Renewal Criteria
	• Improvement in asthma symptoms, asthma exacerbations, or airway function as evidenced by decrease in ≥ 1 of the following:
	  ○ Use of systemic corticosteroids; OR
	  ○ Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days; OR
	  ○ Hospitalizations; OR
	  ○ ER visits; OR

Clinical Criteria Review	Options for Consideration
	○ Unscheduled visits to healthcare provider; OR ○ Improvement from baseline in FEV1; AND • Patient has not experienced any treatment-restricting adverse effects **Age Limit**: ≥ 12 years **Quantity Limit**: 1 prefilled syringe per 28 days

New Class Reviews	Options for Consideration
Immunomodulators, Asthma	**Immunomodulators, Asthma** • DMS to select preferred agent(s) based on economic evaluation. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in *Immunomodulators, Asthma* class, require PA until reviewed by the P&T Committee. **Non-preferred drug criteria** • Approval of non-preferred agents requires ≥ 3-month trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of at least 1 preferred agent.
Uterine Disorder Treatments	**Uterine Disorder Treatments** • DMS to select preferred agent(s) based on economic evaluation. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in *Uterine Disorder Treatments* class, require PA until reviewed by the P&T Committee. **Non-preferred drug criteria** • Approval of non-preferred agents requires trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of 1 preferred agent with the same indication for use.
Full Class Reviews	**Options for Consideration**
Analgesics, Narcotics Short	**Narcotics: Short-Acting** • DMS to select preferred agent(s) based on economic evaluation; however, at least six unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Narcotics: Short-Acting* class, require PA until reviewed by the P&T Advisory Committee.
Analgesics, Narcotics Long Acting	**Narcotics: Long-Acting** • DMS to select preferred agent(s) based on economic evaluation; however, at least four unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Narcotics: Long-Acting* class, require PA until reviewed by the P&T Advisory Committee.
Antihyperuricemics	**Antihyperuricemics** • DMS to select preferred agent(s) based on economic evaluation; however, at least two unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Antihyperuricemics* class, require PA until reviewed by the P&T Advisory Committee.

Antimigraine Agents, Other	**Antimigraine Agents, CGRP Inhibitors** • DMS to select preferred agent (s) based on economic evaluation. • Agents not selected as preferred will be considered non preferred and require PA. • For any new chemical entity in the *Antimigraine Agents, CGRP Inhibitors* class, require a PA until reviewed by the P&T Advisory Committee.
Bone Resorption Suppression & Related	**Bone Resorption Suppression and Related Agents** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Bone Resorption Suppression and Related Agents* class, require PA until reviewed by the P&T Advisory Committee.
Colony Stimulating Factors	**Erythropoiesis Stimulating Proteins** • DMS to select preferred agent (s) based on economic evaluation. • Agents not selected as preferred will be considered non preferred and require PA. • For any new chemical entity in the *Colony Stimulating Factors* class, require a PA until reviewed by the P&T Advisory Committee.
Glucagon Agents	**Glucagon Agents** • DMS to select preferred agent(s) based on economic evaluation; however, at least one intramuscular (IM) glucagon should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Glucagon Agents* class, require PA until reviewed by the P&T Advisory Committee.
Glucocorticoids, Oral	**Oral Steroids** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Oral Steroids* class, require PA until reviewed by the P&T Advisory Committee.
Hypoglycemics, Incretin Mimetics/Enhancers	**Diabetes: DPP-4 Inhibitors** • DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in *Diabetes: DPP-4 Inhibitors* class, require a PA until reviewed by the P&T Advisory Committee.
Hypoglycemics, Insulins & Related	**Diabetes: Insulins and Related Agents** • DMS to select preferred agent(s) based on economic evaluation; however, at least one insulin of each type (short, intermediate, long) should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Diabetes: Insulins and Related Agents* class, require PA until reviewed by the P&T Advisory Committee.

Phosphate Binders	**Phosphate Binders** • DMS to select preferred agent(s) based on economic evaluation; however, at least two unique chemical entities, one of which should be a calcium-based phosphate binder, should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Phosphate Binders* class, require a PA until reviewed by the P&T Advisory Committee.

Consent Agenda	Options for Consideration
For the following therapeutic classes, there are **no recommended changes to the currently posted Preferred Drug List (PDL) status**; these may be voted on as a group:	
• Androgenic Agents • Antimigraine Agents – Triptans (Antimigraine Agents - 5-HT1Receptor Agonists) • Erythropoiesis Stimulating Proteins • Growth Hormone • Hypoglycemics, Alphaglucosidase inhibitors (Diabetes: AlphaGlucosidase Inhibitors) • Hypoglycemics, Incretin Mimetics/Enhancers (Diabetes: GLP-1 Agonists) • Hypoglycemics, Meglitinides (Diabetes: Meglitinides) • Hypoglycemics, Metformins (Diabetes: Metformins) • Hypoglycemics, SGLT2 Inhibitors (Diabetes: SGLT2 Inhibitors)	• Hypoglycemics, Sulfonylureas (Diabetes: Sulfonylureas) • Hypoglycemics, Thiazolidinediones (TZD) (Diabetes: Thiazolidinediones) • Narcotics: Agonist/Antagonists • Narcotics: Fentanyl Buccal Products • Neuropathic Pain • Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) • Opiate Dependence Treatments • Pancreatic Enzymes • Progestins for Cachexia • Skeletal Muscle Relaxants • Thrombopoiesis Stimulating Proteins (Thrombopoiesis Stimulating Agents)