COUPE HEALTH

PHARMACY UTILIZATION MANAGEMENT (UM) PROGRAM CRITERIA ACTIVITY

Provider Notification

Policies Effective: 1/1/2023 Notification Posted: 11/4/2022

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Revisions are effective the first of the month following a 45-day notification and comment period.

NEW UM PROGRAM CRITERIA			
Kerendia (finerenone)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Kerendia (finerenone)

Generic name: finerenone
Brand name: Kerendia
Medispan GPI: 303540300003** MONY
Medication class: Mineralocorticoid (Aldosterone) Receptor Antagonist
FDA-approved uses: **Chronic kidney disease associated with type 2 diabetes**

Usual dose range:

CKD - eGFR ≥60 mL/minute/1.73 m²	Initial: 20mg once daily	Maintenance: dependent on serum potassium levels
CKD - eGFR ≥25 to <60 mL/minute/1.73 m²	Initial: 10mg once daily	Maintenance: dependent on serum potassium levels

Duration of Authorization:
Initial: 4 months
Ongoing: 12 months

Estimated Cost: $8,724.96/yr AWP (all strengths)

Criteria for use for CKD with T2DM

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 18 years of age or older.
- Grandfather criteria allowed
    - Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Patient is clinically diagnosed with adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2DM), at risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure.
    - Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D) defined by one of the following:
        - All of the following:
            - Urinary albumin-to-creatinine ratio (UACR) of 30 to 300 mg/g
            - Estimated glomerular filtration rate (eGFR) 25 to 60 mL/min/1.73 m2
            - Diabetic retinopathy

        -OR-
        - Both of the following:
            - UACR of greater than or equal to 300 mg/g
            - eGFR of 25 to 75 mL/min/1.73 m2
    - Serum potassium level is less than or equal to 5 mEQ/L prior to initiating treatment
- Must be prescribed by, or in consultation with a board-certified endocrinologist, nephrologist, cardiologist.
- Patient has failure, contraindication, or intolerance to:
    - At least ONE of the following:
        - Angiotensin converting enzyme (ACE) inhibitor (captopril, enalapril)
        - Angiotensin II receptor blocker (ARB) (candesartan, valsartan)

    -AND-
    - Jardiance (or eGRF 25 to 30 mL/min/1.73 m^2)
- Maintenance dosing:
    - In patient currently on 10mg/day
        - For serum potassium levels ≤4.8, increase to 20mg/day
        - For serum potassium levels >4.8 to 5.5 continue at 10mg/day
        - For serum potassium levels >5.5 hold and restart 10mg once serum potassium ≤5
    - In patient currently on 20mg/day
        - For serum potassium levels ≤4.8, continue at 20mg/day
        - For serum potassium levels >4.8 to 5.5 continue at 20mg/day
        - For serum potassium levels >5.5 hold and restart 10mg once serum potassium ≤5

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Updated chart notes or other clinical documentation confirming efficacy and tolerability of the requested treatment will be required for all renewal reviews. Submitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient demonstrates adequate compliance as defined as an MPR >80%.
- eGFR remains > 25 mL/minute/1.73 m^2

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Concomitant treatment with strong CYP3A4 inhibitors.
- Patients with adrenal insufficiency.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- eGFR remains <25 mL/minute/1.73 m^2
- Patients with severe hepatic impairment (Child-Pugh Class C).

Special Considerations:

- Consider increased serum potassium monitoring in patients with moderate hepatic impairment; avoid use in patients with severe hepatic impairment.
- In the Finerenone in Reducing Kidney Failure and Disease Progression in Diabetic Kidney Disease (FIDELIO-DKD) trial, patients who could become pregnant were required to have a negative pregnancy test prior to inclusion and use ≥2 effective methods of birth control (at least 1 being a physical barrier) during the study.

References:

1. Kerendia (finerenone) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; July 2021.
2. Bakris GL, Agarwal R, Anker SD, et al; FIDELIO-DKD Investigators. Effect of finerenone on chronic kidney disease outcomes in type 2 diabetes. N Engl JMed. 2020;383(23):2219-2229. doi:10.1056/NEJMoa2025845[PubMed 33264825]

MedOne Clinical Review Subcommittee approval: Date: 11-2-22

Initial adoption: 11-2-22
Revised: 11-2-22
11-2-22 1. Pricing updated based off of AWP (9-25-22)
Effective Date (most recent revisions): 1-1-23

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UM PROGRAM CRITERIA REVISED			
Taltz (ixekizumab)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Taltz	1. Corrected fail first medications in psoriatic arthritis (previously noted as psoriasis vulgaris trials)		

Prior Authorization Approval Criteria

Taltz (ixekizumab)

Generic name: ixekizumab
Brand name: Taltz
Medispan GPI: 9025055400**** MON
Medication class: Antipsoriatic Agent; Anti-interleukin 17A monoclonal antibody
FDA-approved uses: **Ankylosing Spondylitis (AS)**
Nonradiographic axial spondyloarthritis
Plaque Psoriasis (PsO)
Psoriatic Arthritis (PsA)

Usual dose range:

AS	Initial: 160 mg once	Maintenance: 80 mg every 4 weeks
Axial spondyloarthritis	Initial: not indicated	Maintenance: 80 mg every 4 weeks
Plaque psoriasis	Initial: 160 mg once followed by 80 mg at weeks 2,4,6,8,10 and 12	Maintenance: 80 mg every 4 weeks
Plaque psoriasis Pediatric		
<25 kg	Initial: 40 mg once	Maintenance: 20 mg every 4 weeks
25-50 kg	Initial: 80 mg once	Maintenance: 40 mg every 4 weeks
>50 kg	Initial: 160 mg once	Maintenance: 80 mg every 4 weeks
Psoriatic arthritis	Initial: 160 mg once	Maintenance: 80 mg every 4 weeks

Duration of Authorization:

Initial:	4 months
Ongoing:	12 months

Estimated Cost: $7,527 80mg/mL dose ($112,905-127,959) (range dependent on use of loading dose)

Criteria for use for Ankylosing Spondylitis

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 18 years of age or older.
- Grandfather criteria allowed
    - Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Patient is clinically diagnosed with an approved indication.
- Documentation of required baseline screening for viral infections (TB, HepB, HepC, HIV (high risk only)) completed within the last 3 months preceding request for treatment (new starts).
    - or complete treatment for tuberculosis within the last 3 months (e.g. rifampin, isoniazid, pyrazinamide, ethambutol) if positive TB test
- Patient is up to date on all ACIP recommended vaccinations for which they qualify. Live vaccines cannot be used during treatment.
- Must be prescribed by, or in consultation with a Rheumatologist. Consult note must be provided if recommendation was in consultation with specialist.
- Patient has failure, contraindication, or intolerance to at least one prescription strength formulary NSAID.
- Documentation of an adequate trial and failure/intolerance of at least one conventional systemic or non-biologic DMARD is encouraged but not required.
  -AND-
- Patient has failure, contraindication, or intolerance to one of the following Cosentyx, Humira, Enbrel

Criteria for use for Non-radiographic axial spondyloarthritis

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.

- Must be 18 years of age or older.
- Grandfather criteria allowed
    - Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Patient is clinically diagnosed with an approved indication.
- Documentation of required baseline screening for viral infections (TB, HepB, HepC, HIV (high risk only)) completed within the last 3 months preceding request for treatment (new starts).
    - or complete treatment for tuberculosis within the last 3 months (e.g. rifampin, isoniazid, pyrazinamide, ethambutol) if positive TB test
- Patient is up to date on all ACIP recommended vaccinations for which they qualify. Live vaccines cannot be used during treatment.
- Must be prescribed by, or in consultation with a Rheumatologist. Consult note must be provided if recommendation was in consultation with specialist.
- Patient has documented failure (active condition despite 3 months of treatment), contraindication, or intolerance to each of the following for their respective indications: methotrexate, cyclosporine, acitretin, leflunomide, or sulfasalazine
- Patient has failure, contraindication, or intolerance to at least one prescription strength formulary NSAID.
- Documentation of an adequate trial and failure/intolerance of at least one conventional systemic or non-biologic DMARD is encouraged but not required
  -AND-
- Patient has failure, contraindication, or intolerance to Cosentyx

Criteria for use for Plaque Psoriasis

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Grandfather criteria allowed
    - Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Patient is clinically diagnosed with an approved indication.
- Must be 6 years of age or older.
- Documentation of required baseline screening for viral infections (TB, HepB, HepC, HIV (high risk only)) completed within the last 3 months preceding request for treatment (new starts).
    - or complete treatment for tuberculosis within the last 3 months (e.g. rifampin, isoniazid, pyrazinamide, ethambutol) if positive TB test
- Patient is up to date on all ACIP recommended vaccinations for which they qualify. Live vaccines cannot be used during treatment.
- Must be prescribed by, or in consultation with a Dermatologist. Consult note must be provided if recommendation was in consultation with specialist.
- Patient has failure, contraindication, or intolerance to at least one conventional systemic DMARD (acitretin, cyclosporine, methotrexate, sulfasalazine).
- Patient must be a candidate for phototherapy or systemic therapy
- Patient must have 10% or more BSA involvement OR involvement of a sensitive area (hands, feet, face, scalp, or genital area)
- Patient must have failure, intolerance, or contraindication to at least one conventional systemic DMARD (acitretin, cyclosporine, methotrexate, sulfasalazine)
  -AND-

- At least TWO category B medications (Humira, Enbrel, Cosenytx, Stelara, Skyrizi).

Criteria for use for Psoriatic arthritis

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 18 years of age or older.
- Grandfather criteria allowed
    - Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Patient is clinically diagnosed with an approved indication.
- Documentation of required baseline screening for viral infections (TB, HepB, HepC, HIV (high risk only)) completed within the last 3 months preceding request for treatment (new starts).
    - or complete treatment for tuberculosis within the last 3 months (e.g. rifampin, isoniazid, pyrazinamide, ethambutol) if positive TB test
- Patient is up to date on all ACIP recommended vaccinations for which they qualify. Live vaccines cannot be used during treatment.
- Must be prescribed by, or in consultation with a Rheumatologist or Dermatologist. Consult note (documentation of recommendation) must be provided if recommendation was in consultation with specialist.
- Patient must have failure, intolerance, or contraindication to at least ONE conventional systemic DMARD (azathioprine, hydroxychloroquine, methotrexate, leflunomide)
  -AND-
- At least TWO category B medications (Humira, Enbrel, Cosenytx, Stelara, Xeljanz/Xeljanz XR)

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Chart notes evaluating the safety and efficacy from within the prior 12 months are required for reauthorization.
- Patient demonstrates adequate compliance as defined as an MPR >80%.

Contraindications:

- History of hypersensitivity to any of the product ingredients.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patient must not have active tuberculosis infection. Confirm by TB skin test, IGRA, or chest X-ray.

Special Considerations:

- Treatment with ixekizumab may cause or exacerbate Crohn's and Ulceractive Collitis. Patients should be monitored for signs/symptoms of inflammatory bowel disease.
- Infections: May increase the risk of infections. A higher rate of infections was observed with ixekizumab treatment in clinical trials, including upper respiratory tract infection, oral candidiasis, conjunctivitis, and tinea infections. Use with caution in patients with a chronic infection or a history of recurrent infection. In patients who develop a serious infection, monitor closely and discontinue use until the infection resolves.

- Tuberculosis: Patients should be evaluated for tuberculosis (TB) infection prior to initiating therapy; do not initiate therapy in patients with an active TB infection. Consider antituberculosis therapy if an adequate course of treatment cannot be confirmed in patients with a history of latent or active TB. Monitor all patients for signs and symptoms of active TB during and after treatment.
- Immunizations: Patients should be brought up to date with all immunizations before initiating therapy. Live vaccines should not be given concurrently.

References:

3. Taltz ® [package insert]. Indianapolis, IN: Eli Lilly and Co.; March 2016. Revised November 2021.
4. Farahnik B, Beroukhim K, Nakamura M, Abrouk M, Zhu TH, Singh R, Lee K, Bhutani T, Koo J. Anti-IL-17 Agents for Psoriasis: A Review of Phase III Data. J Drugs Dermatol. 2016 Mar 1;15(3):311-6.
5. Genovese MC, Braun DK, Erickson JS, Berclaz PY, Banerjee S, Heffernan MP, Carlier H. Safety and Efficacy of Open-label Subcutaneous Ixekizumab Treatment for 48 Weeks in a Phase II Study in Biologic-naive and TNF-IR Patients with Rheumatoid Arthritis. J Rheumatol. 2016 Feb;43(2):289-97.
6. Leonardi CL, Kimball AB, Papp KA, et al: Efficacy and safety of ustekinumab, a human interleukin-12/23 monoclonal antibody, in patients with psoriasis: 76-week results from a randomised, double-blind, placebo-controlled trial (PHOENIX 1). Lancet 2008; 371(9625):1665-1674.
7. Papp KA, Langley RG, Lebwohl M, et al: Efficacy and safety of ustekinumab, a human interleukin-12/23 monoclonal antibody, in patients with psoriasis: 52-week results from a randomised, double-blind, placebo-controlled trial (PHOENIX 2). Lancet 2008; 371(9625):1675-1684.
8. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6. J Am Acad Dermtol. 2010;65(1):137-174.

MedOne P&T Committee approval: Date: 1/1/17

Initial adoption: 1/1/17

Revised: 4/7/22

2. Ankylosing Spondylitis and Axial spondyloarthritis added as indications.
3. Pricing updated based off of AWP (4/7/22).
4. Added pediatric dosing for plaque psoriasis indication.
5. Added initial and maintenance dosing for AS, Axial spondyloarthritis, and Psoriatic arthritis.
6. Added fail first criteria for Ankylosing Spondylitis to least one conventional systemic or non-biologic DMARD is encouraged but not required -AND- patient has failure, contraindication, or intolerance to one of the following Cosentyx, Humira, Enbrel.
7. Added fail first criteria for Nonradiographic axial spodyloarthritis to least one conventional systemic or non-biologic DMARD is encouraged but not required -AND- patient has failure, contraindication, or intolerance to Cosentyx.
8. Updated fail first criteria for Plaque Psoriasis and Psoriatic arthritis to include failure, intolerance, or contraindication to at least ONE conventional systemic DMARD -AND- At least TWO category B medications.

11-2-22

1. Corrected fail first medications in psoriatic arthritis (previously noted as psoriasis vulgaris trials)

Effective Date (most recent revisions): 1-1-23

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