denotes change in current criteria
denotes new criteria

Tresiba/Toujeo

CLASS PA CRITERIA: Non-preferred agents require a ninety (90) day trial of a pharmacokinetically similar agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

PREVIOUS CRITERIA:

***Toujeo Solostar and Toujeo Max Solostar may be approved only for:

1.) Patients who require once-daily doses of at least 60 units of long-acting insulin and have demonstrated at least a 6-month history of compliance on preferred long-acting insulin and who continue to have regular incidents of hypoglycemia.
OR
2.) Patients who currently require over 200 units per day of long-acting insulin.

PROPOSED CRITERIA:

**Tresiba U-100 may be approved only for: Patients who have demonstrated at least a 6-month history of compliance on a preferred long-acting insulin and who continue to have regular incidents of hypoglycemia. Add grandfathering

**Tresiba U-200 may be approved only for: Patients who require once-daily doses of at least 60 units of long-acting insulin and have demonstrated at least a 6-month history of compliance on preferred long-acting insulin and who continue to have regular incidents of hypoglycemia. Add grandfathering

****Toujeo Max Solostar may be approved only for patients who currently require over 200 units per day of long-acting insulin.

HYPOGLYCEMICS, INSULIN AND RELATED AGENTS

CLASS PA CRITERIA: Non-preferred agents require a ninety (90) day trial of a pharmacokinetically similar agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

APIDRA (insulin gluisine)[AP]* FIASP (insulin aspart) HUMALOG (insulin lispro) HUMALOG JR KWIKPEN (insulin lispro) HUMALOG KWIKPEN U-100 (insulin lispro) HUMALOG MIX PENS (insulin lispro/lispro protamine) HUMALOG MIX VIALS (insulin lispro/lispro protamine) HUMULIN N VIAL (insulin) HUMULIN R U-500 VIAL (insulin) HUMULIN R U-500 KWIKPEN (insulin) LANTUS (insulin glargine) LEVEMIR (insulin detemir) NOVOLOG (insulin aspart) NOVOLOG MIX (insulin aspart/aspart protamine) TOUJEO SOLOSTAR (insulin glargine) TOUJEO MAX SOLOSTAR (insulin glargine)****	ADMELOG (insulin lispro) AFREZZA (insulin)[CL] BASAGLAR (insulin glargine) HUMALOG KWIKPEN U-200 (insulin lispro) HUMULIN PENS (insulin) HUMULIN R VIAL (insulin) HUMULIN 70/30 (insulin) insulin aspart insulin aspart/aspart protamine insulin lispro LYUMJEV (insulin lispro) NOVOLIN (insulin) SEMGLEE (insulin glargine) SOLIQUA (insulin glargine/lixisenatide)** TRESIBA (insulin degludec)*** TRESIBA FLEXTOUCH (insulin degludec)*** XULTOPHY (insulin degludec/liraglutide)**	*Apidra will be authorized if the following criteria are met: 1. Patient is four (4) years of age or older; **and** 2. Patient is currently on a regimen including a longer acting or basal insulin, **and** 3. Patient has had a trial of a similar preferred agent, Novolog or Humalog, with documentation that the desired results were not achieved.. ** Non-preferred insulin combination products require that the patient must already be established on the individual agents at doses not exceeding the maximum dose achievable with the combination product, and require medical reasoning beyond convenience or enhanced compliance as to why the clinical need cannot be met with a combination of preferred single-ingredient agents. **Tresiba U-100 may be approved only for: Patients who have demonstrated at least a 6-month history of compliance on a preferred long-acting insulin and who continue to have regular incidents of hypoglycemia. **Tresiba U-200 may be approved only for: Patients who require once-daily doses of at least 60 units of long-acting insulin and have demonstrated at least a 6-month history of compliance on preferred long-acting insulin and who continue to have regular incidents of hypoglycemia. ****Toujeo Max Solostar may be approved only for patients who currently require over 200 units per day of long-acting insulin.

Dojolvi (triheptanoin)

Dojolvi *is a medium-chain triglyceride indicated as a source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD).*

CRITERIA FOR APROVAL:

1. Patient has confirmed diagnosis of long-chain fatty acid oxidation disorders (LC-FAOD); **AND**

2. Dojolvi must be prescribed by a clinical specialist knowledgeable in appropriate disease-related dietary management; **AND**

3. Patient will NOT receive an additional medium chain triglyceride while taking Dojolvi; **AND**

4. The target recommended daily dosage does not exceed 35% of the patient's total prescribed daily caloric intake (DCI).

Approval Duration:

Initial approval will be for 6 months.

Criteria for reauthorization:

1. Patient must continue to meet initial approval criteria; **AND**
2. Demonstrate continued documented compliance; **AND**
3. Documentation of positive clinical response and/or stabilization to Dojolvi therapy must be provided (such as cardiac function, exercise tolerance, reduction in major clinical events, including hospitalization, decreased incidence of rhabdomyolysis, hypoglycemia, etc.)

Continuation of therapy will be granted for 12 months.

Omnipod ***(addition of diabetologist as allowed prescriber)***

The Omnipod® Insulin Management System is a compact, waterproof, tubeless wearable device that provides up to 72 hours of non-stop insulin delivery. The system comes with a Freestyle blood glucose meter which is built into the Personal Diabetes Manager (PDM) that communicates wirelessly to the pod. The PDM is a separate unit, is NOT waterproof and must be within 5 feet of the pod to communicate with it. ***The pods themselves are not cross-compatible between the original Omnipod system and the Omnipod DASH system. The Omnipod is NOT a continuous glucose monitor.***

Prior authorization requests for the Omnipod insulin management system may be approved if the following criteria are met:

1. Patient must be diagnosed with Type I or Type II Diabetes; **AND**

~~2. Product must be prescribed by (or in documented consultation with) an endocrinologist or diabetologist; **AND**~~

3. Documentation must be submitted indicating that the patient has received diabetic education; **AND**

4. Patient must meet all age restrictions stated in the manufacturer's label; **AND**

5. Patient must have been compliant on their current antidiabetic regimen for at least the last 6 months and this regimen must include multiple daily injections of insulin (requiring at least 3 injections per day); **AND**

6. Documentation (i.e., a glucose log) must be submitted indicating a glucose self-testing frequency of at least 4 times per day during the 3 months prior to the request. a. Documented history of recurring hypoglycemia; OR

b. Wide fluctuations in pre-meal blood glucose, history of severe glycemic excursions or experiencing "Dawn" phenomenon with fasting blood glucose exceeding 200 mg/dL; **OR**

c. Prior use of an insulin pump with documented frequency of glucose self-testing of at least 4 times per day in the month immediately prior to the request.

AND at least one of the following criteria must also be met:
Initial approval of the Omnipod system will be for 6 months. Additional therapy shall be approved with documentation of satisfactory patient response (including current HbA1C).

Fintepla

Fintepla *is indicated for treatment of seizures associated with Dravet syndrome in patients ≥ 2 years of age.*

CRITERIA FOR APROVAL:

1. The patient has a diagnosis of Dravet Syndrome; **AND**
2. The patient must be within the age range as recommended by the FDA label and indication; **AND**
3. Fintepla is prescribed by, or in consultation with a neurologist; **AND**
4. The prescriber, pharmacy, and patient must all be enrolled in the FINTEPLA REMS program; **AND**
5. Documentation of current baseline seizure activity per month must be provided; **AND**
6. The patient must have treatment failure/inadequate response to valproate and clobazam. If there is an intolerance, allergy, or contraindication to valproate, one other preferred antiepileptic (such as topiramate or levetiracetam) must be trialed; **AND**
7. Evaluation with echocardiography is required before treatment, every six months during treatment, and once three to six months after treatment to monitor for valvular heart disease and pulmonary hypertension.

Approval Duration:

Initial approval will be for 6 months.

Criteria for reauthorization:

1. Patient must continue to meet initial approval criteria; **AND**
2. Demonstrate continued documented compliance; **AND**
3. Documented decrease from baseline in seizure frequency per month must be provided.

Continuation of therapy approvals will be granted for 12 months

Xyrem/Xywav *(adding Xywav to established Xyrem criteria)*

Prior authorization requests for Xyrem/Xywav will be approved if the following criteria are met:

1) Diagnosis of narcolepsy with excessive daytime sleepiness (EDS) and/or cataplexy as confirmed by a sleep study followed by multiple sleep latency testing (MSLT); **AND**

2) Being prescribed by a sleep specialist enrolled in the Xywav and Xyrem® REMS Program; **AND**

3) Member is enrolled in Xywav and Xyrem REMS Program; **AND**

4) Member does not have a history or succinic semialdehyde dehydrogenase deficiency; **AND**

5) Member is not receiving concurrent treatment with sedative hypnotics or central nervous system depressants; **AND**

6) Member has a recent drug screen negative for benzodiazepines, opiates, and illicit drugs; **AND**

7) Member has a documented history of alcohol abstinence; **AND**

8) Member does not have a history of substance abuse; **AND**

9) Member does not have a condition which would require a restricted intake of sodium such as, but not limited to, hypertension or stage 4-5 renal impairment.

For narcolepsy with daytime sleepiness, must have documented history of therapeutic failure of the following, as determined by an Epworth Sleepiness scale of greater than or equal to 10 or repeated maintenance of Wakefulness Test (MWT) or MSLT with a mean sleep latency of 8 minutes or less;

1) Modafinil or Armodafinil at maximum recommended doses; **AND**
2) Methylphenidate, methamphetamine or dextroamphetamine at maximum recommended doses; **OR**
3) Intolerance to or contraindication for the above agents

For narcolepsy with cataplexy, must have documented history of therapeutic failure, contraindication, or intolerance to:
1) Tricyclic antidepressants; **AND**
2) SSRIS and SNRIS

Xywav will only be approved upon documentation of allergy, intolerance, or contraindication to Xyrem. Requests for Xywav must be accompanied with the 2 most recent basic metabolic panel (BMP) tests.

Emflaza

EMFLAZA *is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older.*

Prior authorization requests may be approved if the following criteria have been satisfied:

1. Diagnosis of Duchenne muscular dystrophy (DMD); **AND**

2. Patient ≥ 2 years old; **AND**

3. Prescribed by, or in consultation with, a neurologist or a specialist in Duchenne Muscular Dystrophy (DMD) or neuromuscular disorders; **AND**

4. Patient must have a documented history of at least ~~12-months~~ 6-months continuous therapy with prednisone, unless contraindicated; **AND**

5. Documentation must be submitted indicating that the patient has experienced significant adverse effects associated with prednisone therapy. Documentation must include a detailed description of the adverse effect; as the side effect profiles are similar between deflazacort and prednisone, prior authorization shall only be granted for those patients experiencing side effects where deflazacort shows an improved profile. Significant adverse effects are defined as:

   a. Patient has manifested significant psychiatric or behavioral changes negatively impacting function at school, day care, etc; **OR**

   b. Patient has experienced Cushingoid effects or significant weight gain (crossing 2 percentiles and/or reaching 98th percentile for age and sex); **AND**

6. Request must be accompanied with ~~a baseline 6-minute walk distance (6MWD)~~ baseline clinical criteria used to assess the patient by at least **one of the following** tests:

   a) Muscle strength tests (such as, Medical Research Council [MRC] scale for muscle strength with 0 being no movement and 5 being normal strength), or
   b) Motor (walk) tests (such as 6-minute walk test [6MWT] distance), or
   c) Pulmonary function tests (such as, forced vital capacity [FVC] and maximal expiratory pressure), or
   d) Timed functional tests (such as, standing from lying position; climbing 4 stairs; running/walking 30 feet; propelling a wheelchair 30 feet).

~~**7.** Initial authorizations shall be for 90 days. Continuation requests may be granted a 12-month approval if significant improvement is demonstrated in either the patient's adverse effect profile or 6MWD.~~

Approval Duration:

Initial approval: will be for 6 months.

Criteria for reauthorization:

1. Patient must continue to meet initial approval criteria; **AND**
2. Demonstrate continued documented compliance; **AND**
3. Documentation that adverse events associated with prednisone therapy were resolved through treatment with Emflaza; **OR**
4. Documented evidence with the most recent results (≤ 6 months prior to request) must be submitted showing clinically significant improvement in DMD associated symptoms, stabilization or lack of progression as compared to the natural history trajectory of the disease demonstrated by at least **one of the following** from pre-treatment baseline status:

    a) Muscle strength tests (such as, Medical Research Council [MRC] scale for muscle strength with 0 being no movement and 5 being normal strength), or
    b) Motor (walk) tests (such as 6-minute walk test [6MWT] distance), or
    c) Pulmonary function tests (such as, forced vital capacity [FVC] and maximal expiratory pressure), or
    d) Timed functional tests (such as, standing from lying position; climbing 4 stairs; running/walking 30 feet; propelling a wheelchair 30 feet).

Continuation of therapy approvals will be granted for 12 months.

Multiple Sclerosis Agents

All agents require a prior authorization and documented diagnosis of multiple sclerosis. Preferred oral agents require a ninety (90) day trial of any preferred injectable agent. Non-preferred agents require ninety (90) day trials of each chemically unique preferred agent (in the same sub-class) before they will be approved, unless one (1) of the exceptions on the PA form is present.

All agents require a prior authorization and documented diagnosis of multiple sclerosis. Preferred oral agents require a ninety (90) day trial of any preferred injectable agent. Non-preferred agents require ninety (90) day trials of two (2) chemically unique preferred agents (in the same sub-class) before they will be approved, unless one (1) of the exceptions on the PA form is present.

MULTIPLE SCLEROSIS AGENTS[CL]		
CLASS PA CRITERIA: All agents require a prior authorization and documented diagnosis of multiple sclerosis. Preferred oral agents require a ninety (90) day trial of any preferred injectable agent. Non-preferred agents require ninety (90) day trials of two (2) chemically unique preferred agent (in the same sub-class) before they will be approved, unless one (1) of the exceptions on the PA form is present.		
INTERFERONS[AP]		
AVONEX (interferon beta-1a) AVONEX PEN (interferon beta-1a) BETASERON (interferon beta-1b) REBIF (interferon beta-1a) REBIF REBIDOSE (interferon beta-1a)	EXTAVIA KIT (interferon beta-1b) EXTAVIA VIAL (interferon beta-1b) PLEGRIDY (peginterferon beta-1a)	
NON-INTERFERONS		
AUBAGIO (teriflunomide)* dalfampridine ER**	AMPYRA (dalfampridine)** BAFIERTAM CAPSULES (monomethyl fumarate)	**In addition to class PA criteria, the following conditions and criteria may also apply:**
COPAXONE 20 mg (glatiramer) GILENYA (fingolimod) TECFIDERA (dimethyl fumarate)***	COPAXONE 40 mg (glatiramer)**** dimethyl fumerate*** glatiramer GLATOPA (glatiramer) KESIMPTA INJECTION (ofatumumab) MAYZENT (siponimod)***** MAVENCLAD (cladribine) VUMERITY (diroximel) ZEPOSIA (ozanimod)	*Aubagio requires the following additional criteria to be met: 1. Diagnosis of relapsing multiple sclerosis **and** 2. Measurement of transaminase and bilirubin levels within the (6) months before initiation of therapy and ALT levels at least monthly for six (6) months after initiation of therapy **and** 3. Complete blood cell count (CBC) within six (6) months before initiation of therapy **and** 4. Female patients must have a negative pregnancy test before initiation of therapy and be established on a reliable method of contraception if appropriate **and** 5. Patient is between eighteen (18) up to sixty-five (65) years of age **and** 6. Negative tuberculin skin test before initiation of therapy **Dalfampridine ER and Ampyra require the following additional criteria to be met: 1. Diagnosis of multiple sclerosis **and** 2. No history of seizures **and** 3. No evidence of moderate or severe renal impairment. ***Dimethyl fumerate and Tecfidera require the following additional criteria to be met: 1. Diagnosis of relapsing multiple sclerosis **and** 2. Complete blood count (CBC) within six (6) months of initiation of therapy and six (6) months after initiation **and** 3. Complete blood count (CBC) annually during therapy. ****Copaxone 40mg will only be authorized for documented injection site issues. *****Mayzent may be authorized with no additional requirement beyond the diagnosis for patients with documented secondary progressive MS.
NEUROPATHIC PAIN		

Amondys 45

AMONDYS 45 is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping. This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with AMONDYS 45. **A clinical benefit of AMONDYS 45 has not been established.** Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

AMONDYS 45 may be billed as a Medical ("Buy & Bill") claim OR as a Pharmacy Point-of-Sale (POS) claim:

• Medical "Buy & Bill" under J3490 - Contact KEPRO, tel: (304) 343-9663/ fax (866) 209-9632

• Pharmacy POS - Contact RDTP, tel: (800) 847-3859/ fax (800) 531-7787

All requests require review by the Medical Director and may be approvable once the following criteria are met:

1. Patient must have a confirmed mutation of a DMD gene that is amenable to exon 45 skipping (chart notes required); **AND**

2. The patient must meet all label requirements as recommended by the FDA and the manufacturer; **AND**

3. Baseline renal function must be evaluated, and documentation provided with the request for Amondys 45; **AND**

4. Request must either be from a neurologist or from a physician who has provided documentation of a formal consultation with a neurologist; **AND**

Patient must be stabilized on corticosteroid therapy for at least 6 months prior to the request for coverage of Amondys 45. Documentation must be supplied detailing the prescribed steroid therapy and the patient must continue this therapy while receiving Amondys 45.

NOTE: If the patient cannot take steroid therapy, clinical justification must be provided by the physician, otherwise the prior authorization request shall be immediately denied; **AND**

5. The results of appropriate and validated baseline functional tests must be submitted with the initial request for therapy. These results will be considered valid only if taken after the patient has received corticosteroid therapy for at least 6 months.

Acceptable tests may include, **but are not limited to**, any of the following:

a. Ambulatory patients: Six-minute walk test (6MWDT) (patient must achieve > 180 meters for approval.

b. Non-ambulatory patients: Brooke Upper Extremity Function Scale (of 5 or less) **AND** a Forced Vital Capacity of ≥ 30% of predicted value are required for approval.

Other functional assessment tests may be accepted on a case-by-case basis at the discretion of the Medical Director. These tests must be quantitative in nature and accompanied with supporting documentation and references describing the test.

All prior authorization approvals are limited to 6 months at time and continuation of coverage requires the following conditions to be met:

1) Follow-up functional test results must show stabilization or improvement of patient function compared to baseline measures; **AND**

2) The results of regular renal function tests (as recommended by the manufacturer*) must be supplied with every request for Amondys 45; **AND**

3) Patient must maintain 100% compliance on all scheduled therapy – Amondys 45 must be dosed once per week and maintenance steroid therapy must continue as prescribed by the physician. Failure to maintain compliance with prescribed therapy shall result in immediate discontinuation of coverage unless the disruption can be medically justified by the prescribing physician.

*****The following are recommended by the manufacturer: Measurement of glomerular filtration rate (GFR) by 24-hour urine collection prior to initiation of therapy, monitoring for proteinuria by dipstick urinalysis at baseline and monthly, monitoring of serum cystatin C and urine protein-to-creatinine ratio (UPCR) every three months. If a persistent increase in serum cystatin C or proteinuria is detected, refer to a pediatric nephrologist for further evaluation.

Verquvo

Verquvo *is a soluble guanylate cyclase (sGC) stimulator, indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.*

CRITERIA FOR APROVAL:

1. The patient must have a diagnosis of symptomatic chronic heart failure (New York Heart Association [NYHA] class II-IV); **AND**

2. Patient must be ≥ 18 years of age; **AND**

3. Patient must have a left ventricular ejection fraction (LVEF) less than 45%; **AND**

4. Verquvo must be prescribed by, or in consultation with, a cardiologist; AND

5. Documentation of recent hospitalization (within the past 6 months) due to CHF or a demonstrated need for outpatient IV diuretics (within the past 3 months) must be provided; **AND**

6. Women of childbearing potential must have a negative pregnancy test collected prior to therapy initiation; **AND**

7. The patient may not use Verquvo with another soluble guanylate cyclase (sGC) stimulator or a phosphodiesterase-5 (PDE-5) inhibitor; **AND**

8. The patient must have been optimized on combination therapy consisting of **ONE** agent from **EACH** of the following classes, unless contraindicated:

    a. ACE inhibitor, ARB, or Angiotensin Receptor-Neprilysin Inhibitor (ARNI)
    b. Beta-blocker
    c. Mineralocorticoid receptor antagonist (Aldosterone antagonist) (where indicated*)
    ~~d. SGLT-2~~

* **For patients with persistent symptoms on initial therapy** – For patients with HFrEF who have symptomatic HF (New York Heart Association [NYHA] class II, III, or IV and an LVEF ≤35 percent on optimal initial pharmacologic therapy, addition of an MRA is recommended

For patients post-myocardial infarction with LVEF ≤40 percent – For patients post myocardial infarction (MI) with an LVEF ≤40 percent who are already receiving a renin angiotensin system inhibitor and have either symptomatic HF or diabetes mellitus (DM), addition of MRA is recommended.

Approval Duration:

Initial approval: will be for 6 months.

Criteria for reauthorization:

1. Patient must continue to meet initial approval criteria; **AND**
2. Demonstrate continued documented compliance; **AND**
3. Documentation is provided that indicated the patient has experienced positive clinical benefit while taking Verquvo (such as a decrease in hospitalizations, improvement in heart failure symptoms, reduction in need of IV diuretics).

Continuation of therapy approvals will be granted for 12 months.

Benlysta

Benlysta *is indicated for the treatment of adults and children ≥5 years of age with active, autoantibody-positive systemic lupus erythematosus (SLE) who are receiving standard therapy or treatment of adults with active lupus nephritis who are receiving standard therapy.*

Prior authorization requests for Benlysta may be approved if the following criteria are met:

1. Documented diagnosis of active systemic lupus erythematosus (SLE) or Lupus Nephritis ; **AND**

2. The patient is positive for autoantibodies (anti-nuclear antibody (ANA) and anti-double-stranded DNA (anti-dsDNA); **AND**

3. The patient must be within the age range as recommended by the FDA label and indication; **AND**

4. Prescribed by, or in consultation with, a rheumatologist or nephrologist; **AND**

5. **For SLE**: The patient has had a documented inadequate response or intolerance to at least **TWO** of the following agents: non-steroidal anti-inflammatory drugs (NSAIDS), hydroxychloroquine, corticosteroids, methotrexate, azathioprine, cyclosporine, or mycophenolate; **AND**

6. **For LN:** Patient has failed to respond adequately to standard therapies including corticosteroids **AND** cyclophosphamide, mycophenolate mofetil or azathioprine.

Initial approval will be granted for 3 months.

NOTE: Use is not recommended in patients with severe active lupus nephritis, severe active CNS lupus, or in combination with other biologics, including B-cell targeted therapies or IV cyclophosphamide. Use of Benlysta should be avoided and is not recommended in these situations.

CONTINUATION OF THERAPY CRITERIA:
Clinical documentation must be submitted documenting stability/reduction in disease activity OR a reduction in corticosteroid dose.

Lupkynis

***Lupkynis**, a calcineurin inhibitor immunosuppressant, is indicated in combination with a background immunosuppressive therapy regimen for the treatment of adults with active **lupus nephritis**.*

CRITERIA FOR APROVAL:

1. The patient must have a diagnosis of active lupus nephritis (LN); **AND**

2. Patient is positive for autoantibodies (anti-nuclear antibody [ANA] and anti-double-stranded DNA [anti-dsDNA]); **AND**

3. Patient has International Society of Nephrology/Renal Pathology Society (ISN/RPS) biopsy-proven active Class III or IV lupus nephritis alone or in combination with Class V lupus nephritis; **AND**

4. Patient has Urine protein to creatinine (UPCR) ratio ≥ 1.5 mg/mg for Class III or IV OR UPCR ≥ 2 mg/mg for Class V; **AND**

5. Patient must be ≥ 18 years of age; **AND**

6. Patient has an estimated glomerular filtration rate (eGFR) > 45 mL/min/m2; **AND**

7. Lupkynis must be prescribed by, or in consultation with, a nephrologist or rheumatologist; **AND**

8. Patient is using (for a minimum of 3-months) and will continue to use background immunosuppressive therapy for LN with a corticosteroid ***AND*** mycophenolate mofetil or azathioprine; **AND**

9. Patient must have been trialed on Benlysta for ninety (90) days and experienced inadequate response or therapeutic failure, unless otherwise contraindicated.

Approval Duration:

Initial approval: will be for 3 months.

An additional 3 months of therapy may be granted if the following criteria are met:

1. Patient must continue to meet initial approval criteria; **AND**
2. Demonstrate continued documented compliance; **AND**
3. There is no evidence of toxicity from Lupkynis; **AND**
4. Documentation is provided indicating stabilization of disease or an absence of disease progression.

Note: Safety and efficacy have not been established in combination with cyclophosphamide and is not recommended. The recommended starting dose is 23.7 mg twice daily taken on an empty stomach, used in combination with mycophenolate mofetil and corticosteroids. Dose modifications are required based on estimated glomerular filtration rate (eGFR). Lupkynis is not recommended if baseline eGFR is ≤ 45 mL/min/1.73 m2 unless the benefit exceeds the risk. The manufacturer recommends discontinuation of Lupkynis if therapeutic benefit is not apparent by Week 24.

All requests for additional therapy beyond 24 weeks may be considered on a case-by-case basis by the medical director.

Oxlumo

Oxlumo is a *HAO1*-directed small interfering ribonucleic acid (siRNA) *indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels in pediatric and adult patients*.

CRITERIA FOR APROVAL:

1. The patient has a documented diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by either

    a. Genetic testing that demonstrates a mutation of the alanine:glyoxylate aminotransferase (*AGXT*) gene; or

    b. Liver biopsy demonstrating absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) enzyme activity; **AND**

2. Oxlumo is prescribed by, or in consultation with, a nephrologist, a neurologist or other healthcare provider with expertise in treating PH1; **AND**

3. The patient has not had a prior a liver transplant.

Approval Duration:

Initial approval: will be for 6 months.

Criteria for reauthorization:

1. Patient must continue to meet initial approval criteria; **AND**
2. Demonstrate continued documented compliance; **AND**
3. Documentation is provided indicating a positive clinical response to therapy from pre-treatment baseline (such as a reduction in urinary oxalate concentrations, decreased urinary oxalate:creatinine ratio, decreased plasma oxalate concentrations)

Continuation of therapy approvals will be granted for 12 months.

Analgesics, Narcotic Long Acting

CLASS PA CRITERIA: Non-preferred agents require six (6) day trials of two (2) chemically distinct preferred agents **AND** a six (6) day trial of the generic form of the requested non-preferred agent (if available) before they will be approved, unless one (1) of the exceptions on the PA form is present. If no generic form is available for the requested non-preferred brand agent, then another generic non-preferred agent must be trialed instead. **NOTE: All long-acting opioid agents require a prior authorization for children under 18 years of age.** Requests must be for an FDA approved age and indication and specify previous opioid and non-opioid therapies attempted.

CLASS PA CRITERIA: Non-preferred agents require six (6) day trials of three (3) chemically distinct preferred agents **AND** a six (6) day trial of the generic form of the requested non-preferred agent (if available) before they will be approved, unless one (1) of the exceptions on the PA form is present. If no generic form is available for the requested non-preferred brand agent, then another generic non-preferred agent must be trialed instead. **NOTE: All long-acting opioid agents require a prior authorization for children under 18 years of age.** Requests must be for an FDA approved age and indication and specify previous opioid and non-opioid therapies attempted.

*Nucynta requires six (6) day trials of three (3) chemically distinct preferred agents.

ANALGESICS, NARCOTIC LONG ACTING (Non-parenteral)[AP]

CLASS PA CRITERIA: Non-preferred agents require six (6) day trials of three (3) chemically distinct preferred agents **AND** a six (6) day trial of the generic form of the requested non-preferred agent (if available) before they will be approved, unless one (1) of the exceptions on the PA form is present. If no generic form is available for the requested non-preferred brand agent, then another generic non-preferred agent must be trialed instead. **NOTE: All long-acting opioid agents require a prior authorization for children under 18 years of age.** Requests must be for an FDA approved age and indication and specify previous opioid and non-opioid therapies attempted.

BUTRANS (buprenorphine) fentanyl transdermal 12, 25, 50, 75, 100 mcg/hr morphine ER tablets tramadol ER tablets (generic Ultram ER) XTAMPZA ER (oxycodone)	ARYMO ER (morphine sulfate) BELBUCA (buprenorphine buccal film)* buprenorphine patch (all labelers including 00093) CONZIP ER (tramadol) fentanyl transdermal 37.5, 62.5, 87.5 mcg/hr hydromorphone ER HYSINGLA ER (hydrocodone) hydrocodone ER capsule (generic Zohydro) KADIAN (morphine) methadone** MORPHABOND ER (morphine sulfate) morphine ER capsules (generic for Avinza) morphine ER capsules (generic for Kadian) MS CONTIN (morphine) NUCYNTA ER (tapentadol)**** oxycodone ER OXYCONTIN (oxycodone) oxymorphone ER	*Belbuca prior authorization requires manual review. Full PA criteria may be found on the PA Criteria page by clicking the hyperlink. **Methadone will be authorized without a trial of the preferred agents if a diagnosis of cancer is submitted. ***Tramadol ER (generic Conzip) requires a manual review and may be authorized for ninety (90) days with submission of a detailed treatment plan including anticipated duration of treatment and scheduled follow-ups with the prescriber. ****Nucynta ER requires six (6) day trials of three (3) chemically distinct preferred agents.
	tramadol ER (generic Conzip ER)*** ULTRAM ER (tramadol) ZOHYDRO ER (hydrocodone)	