Louisiana ~~Fee-for-Service~~ Medicaid
Androgenic Agents

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request prior authorization for androgenic agents. ~~(excluding oxandrolone).~~

	~~**Generic Name (Brand Example)**~~
	~~Methyltestosterone Capsules (Android®)~~
	~~Testosterone Buccal System (Striant®)~~
	~~Testosterone Cypionate~~
	~~Testosterone Enanthate~~
~~¥ *~~	~~Testosterone Gel (Fortesta®, Testim®, Vogelxo®)~~
	~~Testosterone Pellets (Testopel®)~~
~~¥ *~~	~~Testosterone Topical Solution (Axiron®)~~
~~¥ *~~	~~Testosterone Transdermal Gel (Androgel® Packet, Androgel® Pump)~~
~~¥~~	~~Testosterone Transdermal Patch (Androderm®)~~
~~* †~~	~~Testosterone Undecanoate (Aveed®)~~

~~¥ Topical agents are also part of the preferred / non-preferred drug list.~~
~~* These medications have Black Box Warnings and/or may be subject to Risk Evaluation and Mitigation Strategy (REMS) under FDA safety regulations; refer to individual prescribing information for details.~~
~~† These medications are subject to Risk Evaluation and Mitigation Strategy (REMS) under FDA safety regulations; refer to individual prescribing information for details.~~

*~~NOTE: T~~Some of these agents may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval criteria ~~for both preferred and nonpreferred androgenic agents (one of the following must be met, A or B):~~

~~A. **ALL** of the following:~~

- ~~The recipient is established on the requested medication with positive clinical outcomes; **AND**~~
- ~~Recipient's most current hematocrit level (within the past 3 – 6 months or the past 12 months depending on duration of treatment) is provided on the request and continues to be less than 54%; **AND**~~
- Previous use of a preferred product ~~of a preferred product – t~~ **~~ONE~~** of the following ~~is required~~conditions apply:
  - ~~There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**~~
  - There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**

- The recipient has had a *treatment failure* with at least one preferred drug that is appropriate to use for the condition being treated~~product~~; **OR**
- The recipient has had an *intolerable side effect* to at least one preferred drug that is appropriate to use for the condition being treated~~product~~; **OR**
- The recipient has *documented contraindication(s)* to all of the preferred ~~products~~ drugs that are appropriate to use for the condition being treated; **OR**
- There is *no preferred product that is appropriate* to use for the condition being treated; **AND**

~~**OR**~~

~~B. **ALL** of the following:~~

~~• Requests must include patient-specific documentation of FDA-approved indications **AND** for hypogonadism in adult males; an associated medical condition must be included with requests. Indications and medical conditions are limited to specific agents as summarized in Tables 1-3.~~

~~a. Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.~~

~~b. Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.~~

~~c. Delayed puberty in males: to induce pubertal changes in hypogonadal males~~

~~d. In women as secondary treatment with advancing inoperable metastatic (skeletal) breast cancer who are 1 to 5 years postmenopausal. This treatment has also been used in premenopausal women with breast cancer who have benefited from oophorectomy and are considered to have a hormone-responsive tumor; **AND**~~

~~• All initial requests must include baseline hematocrit levels. Hematocrit levels should be reevaluated at 3 to 6 months and then annually, if therapy continues for that duration; **AND**~~

~~*Approval Criteria: Less than or equal to 54%*~~

~~• Initial requests for use in hypogonadism must also include laboratory results (with date and time drawn) for 2 serum testosterone levels drawn between 8:00 AM and 10:00 AM obtained on different days; **AND**~~

~~*Approval Criteria: Less than 300 ng/dL on both days **OR** below the lower limit of normal on both days for the individual reporting laboratory (must provide documentation of normal limits for individual reporting laboratory)*~~

~~• For requests for use in delayed puberty in males, by submitting the request, the prescriber is attesting to the fact that x-rays of hand and wrist will be performed prior to initiation of requested agent and every 6 months during treatment.; **AND**~~

- ~~For requests for use in breast cancer, by submitting this request, the prescriber is attesting to the fact that the following will be monitored every 6 months:~~

~~a. Hypercalcemia~~
~~b. Liver function tests~~
~~c. Hematocrit level; **AND**~~

- ~~All requests must conform to age limitations as defined in the prescribing information for each agent; **AND**~~

- ~~Previous use of a preferred product – **ONE** of the following is required:~~
  - ~~There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**~~
  - ~~The recipient has had a *treatment failure* with at least one preferred product; **OR**~~
  - ~~The recipient has had an *intolerable side effect* to at least one preferred product; **OR**~~
  - ~~The recipient has *documented contraindication(s)* to the preferred products that are appropriate to use for the condition being treated; **OR**~~
  - ~~There is *no preferred product that is appropriate* to use for the condition being treated; **AND**~~

- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use ~~of the requested medication.~~ of androgenic agents per FDA labeling.

- ~~**Reauthorization Criteria****Authorization renewal based upon the following criteria (ALL conditions must be met):**~~

- The ~~R~~recipient continues to meet initial approval criteria; **AND**
- ~~Recipient is tolerating and is adherent to current treatment; **AND**~~
- The ~~R~~recipient has had a positive ~~clinical outcomes~~response to treatment, and this is **stated on the request**.

Duration of initial and re~~A~~authorization a~~A~~pproval: 6 months~~for All Agents~~
~~**Initial Approval: 6 months**~~
~~**Reauthorization Approval: 6 months**~~

Additional edits may apply at Point-of-Sale (POS). Override options may be available. For more information, refer to the Louisiana Department of Health Pharmacy Benefits Management Services Manual at www.lamedicaid.com/provweb1/Providermanuals/manuals/PHARMACY/PHARMACY.pdf

Table 1. FDA Indications and Associated Medical Conditions for Oral Testosterone Agent	
FDA Indication	**Methyltestosterone**
Primary Hypogonadism (congenital or acquired) a) cryptorchidism	Yes
b) bilateral torsion	Yes
c) orchitis	Yes
d) vanishing testis syndrome	Yes
e) orchiectomy	Yes
f) Klinefelter's Syndrome	No
g) chemotherapy	No
h) toxic damage from alcohol or heavy metals	No
Hypogonadotropic Hypogonadism (congenital or acquired) a) gonadotropin or LHRH deficiency	Yes
b) pituitary hypothalamic injury from trauma, tumors, or radiation	Yes
Delayed Puberty in Males	Yes
Inoperable Female Metastatic (Skeletal) Breast Cancer	Yes

~~**Table 3. FDA Indications and Associated Medical Conditions for Topical, Transdermal, Buccal, and Nasal Testosterone Agents**~~

~~**Table 2. FDA Indications and Associated Medical Conditions for Injectable Testosterone Agents**~~

~~**FDA Indication**~~	~~***Topical Gel***~~	~~***Topical Solution***~~	~~***Transdermal Patch***~~	~~***Buccal***~~	~~***Nasal Gel***~~
	~~**Androgel®, Fortesta®, Testim®, Vogelxo®**~~	~~**Axiron®**~~	~~**Androderm®**~~	~~**Striant®**~~	~~**Natesto®**~~
~~Primary Hypogonadism (congenital or acquired)~~ ~~a) cryptorchidism~~ ~~b) bilateral torsion~~ ~~c) orchitis~~ ~~d) vanishing testis syndrome~~ ~~e) orchiectomy~~ ~~f) Klinefelter's Syndrome~~ ~~g) chemotherapy~~ ~~h) toxic damage from alcohol or heavy metals~~	~~Yes~~	~~Yes~~ ~~Yes~~ ~~Yes~~ ~~Yes~~ ~~Yes~~ ~~Yes~~ ~~No~~ ~~No~~ ~~No~~ ~~No~~	~~Yes~~ ~~Yes~~ ~~Yes~~ ~~Yes~~ ~~No~~ ~~No~~ ~~No~~	~~Yes~~ ~~Yes~~ ~~Yes~~ ~~Yes~~ ~~Yes~~ ~~No~~ ~~No~~ ~~No~~	~~Yes~~ ~~Yes~~ ~~Yes~~ ~~Yes~~ ~~Yes~~ ~~Yes~~ ~~Yes~~ ~~No~~
~~Inoperable Female Hypogonadotropic Hypogonadism (congenital or acquired)~~ ~~a) gonadotropin or LHRH deficiency~~ ~~b) pituitary hypothalamic injury from trauma, tumors, or radiation~~	~~No~~	~~No~~ ~~Yes~~ ~~Yes~~	~~No~~ ~~Yes~~ ~~Yes~~	~~No~~ ~~Yes~~ ~~Yes~~	~~No~~ ~~Yes~~ ~~Yes~~
~~**Delayed Puberty in Males**~~	~~Yes~~	~~No~~	~~Yes~~	~~No~~
~~**Inoperable Female Metastatic (Skeletal) Breast Cancer**~~	~~No~~	~~No~~	~~Yes~~	~~No~~

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Louisiana ~~Fee-for-Service~~ Medicaid
Histamine II Receptor Blockers (H_2 Antagonists)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request authorization for non-preferred agents in this therapeutic category.

~~Pharmacy claims for acute (initial treatment) dosing of H_2 antagonists for recipients 16 years of age and older will process for payment for up to 90 days duration of therapy each calendar year. Claims for recipients under 16 years of age are excluded from this edit.~~
~~For use beyond 90 days duration of therapy, an appropriate diagnosis code is required at Point-of-Sale. Refer to the Pharmacy Provider Manual for more information at https://www.lamedicaid.com/provweb1/Providermanuals/manuals/PHARMACY/PHARMACY.pdf [Pages 133-135 of the 289 page electronic pdf document].~~

Approval criteria for non-preferred agents (both initial and reauthorization): ~~)~~

- For a non-preferred agent, the following conditions apply:
  - There is no preferred alternative that is exactly the ~~exact~~ same chemical entity, formulation, strength, etc.; **AND**
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated: **OR**
  - There is a medical need for a non-preferred dosage form; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no inappropriate concomitant drug therapies or disease states.

Duration of authorization approval, both initial and reauthorization: 12 months

Duration of therapy limit for H_2 receptor blockers:

All H_2 receptor blockers are subject to a duration of therapy limit. This limit is 180 days in a rolling 365-day period (this does not apply to recipients under 16 years of age). For use beyond 180 days duration, an appropriate diagnosis code is required at Point-of-Sale (See page 2 for the list of acceptable diagnosis codes in Table 1).

Table 1. Diagnosis Codes Exempt from the Duration of Therapy Limit for H_2 Receptor Blockers

Abscess of Esophagus	K20.8
Barrett's Esophagus	K22.7*
Crohn's Disease	K50.*
Chronic Pancreatitis	K86.0, K86.1
Duodenal Ulcer	K26.*
Esophagitis, Unspecified	K20.9
Gastric Hyperacidity	K30
Gastric Ulcer	K25.*
Gastritis/Duodenitis	K29.*
Gastroesophageal Reflux Disease (GERD)	K21.9
Gastrointestinal Hemorrhage	K92.2
~~*H. pylori*~~	~~B96.81~~
Malignant Mast Cell Tumors	C96.2
Multiple Endocrine Adenomas	D44.0, D44.2, D44.9
Peptic Ulcer	K27.*
Reflux Esophagitis	K21.0
Ulcer of Esophagus with OR without Bleeding	K22.1*
Zollinger-Ellison Syndrome	E16.4

* Any number or letter or combination of **UP TO FOUR** numbers and letters of an assigned ICD-10-CM diagnosis code

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Revision	**Date**
Modify maximum duration of therapy from 90 days to 180 days, modify definition of year from calendar year to rolling 365-days, remove H. pylori from exemption diagnosis chart, combine PA criteria document with duration of therapy document	November 2019

Louisiana ~~Fee-for-Service~~ Medicaid
Proton Pump Inhibitors (PPIs)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request authorization for non-preferred agents in this therapeutic category and to request an override of the PPI duration of therapy limit for both preferred and non-preferred agents.

Approval criteria for non-preferred agents (both initial and reauthorization)

- For a non-preferred agent, the following conditions apply:
  - There is no preferred alternative that is exactly the ~~exact~~ same chemical entity, formulation, strength, etc.~~;~~ **AND**
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to the preferred products that are appropriate for the condition being treated; **OR**
  - There is *no preferred product appropriate* to use for the condition being treated and/or the age of the recipient; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no inappropriate concomitant drug therapies or disease states.

Duration of authorization approval, both initial and reauthorization: 4 months

~~Maximum~~ Duration of ~~PPI~~ Therapy Limit for PPIs

All PPIs are subject~~In addition~~ to a~~the above criteria, maximum~~ duration of therapy limit. ~~(this does not~~edits apply. ~~Pharmacy claims for PPIs will process for payment for up to~~ recipients ~~under 6 years of age.)~~ This limit is 180~~120~~ days in a rolling 365-day period (this does not apply to recipients under 6 years of age). ~~duration of therapy each fiscal year, which begins July 1 each year and continues through June 30 of the next year.~~ The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request an override of~~to exceed~~ the 180~~120~~-day duration of therapy limit~~limits~~ for both preferred and non-preferred PPIs for recipients to ~~for~~ whom an exemption does~~the exemptions do~~ not apply. (See page 2 for diagnosis code exemptions listed in Table 1.~~).~~ ~~.) Refer to the Pharmacy Provider Manual for more information at https://www.lamedicaid.com/provweb1/Providermanuals/manuals/PHARMACY/PHARMACY.pdf [Pages 136 and 137].~~

Duration of therapy exemptions for PPIs

~~**Pharmacy claims for PPIs are exempt at Point-of-Sale from the duration of therapy limit for:**~~

- Recipients under six (6) years of age; **OR**
- Recipients receiving pancreatic enzymes; **OR**
- Recipients with one of the diagnosis codes in Table 1.

Table 1. Diagnosis Codes Exempt from the Duration of Therapy Limit for PPIs

Abscess of Esophagus	K20.8
Angiodysplasia of Stomach and Duodenum (with OR without Mention of Hemorrhage)	K31.81*
Atrophic Gastritis with Hemorrhage	K29.41
Barrett's Esophagus	K22.7*
Cerebral Palsy (*new Aug 2019*)	G80*
Chronic Pancreatitis	K86.0, K86.1
Congenital Tracheoesophageal Fistula	Q39.1, Q39.2
Cystic Fibrosis	E84.*
Eosinophilic Esophagitis	K20.0
Eosinophilic Gastritis	K52.81
Gastrointestinal Hemorrhage	K92.2
Gastrointestinal Mucositis (Ulcerative)	K92.81
Malignant Mast Cell Tumors	C96.2
Multiple Endocrine Adenomas	D44.0, D44.2, D44.9
Tracheoesophageal Fistula	J86.0
Ulcer of Esophagus with OR without Bleeding	K22.1*
Zollinger-Ellison Syndrome	E16.4

* any number or letter or combination of **UP TO FOUR** numbers and letters of an assigned ICD-10-CM diagnosis code

Approval for a maximum duration of therapy override request will be granted for the following:

- Recipients who have a documented upper GI testing in the previous 2-year period; **OR**
- Recipients who are dependent on a feeding tube for nutritional intake; **OR**
- Recipients receiving a concomitant medication that increases the risk of upper GI bleed (e.g., anticoagulants, antiplatelets, NSAIDs); **OR**
- ~~Recipients with a diagnosis of Cerebral Palsy; **OR**~~
- Recipients who reside in a long-term care facility; **OR**
- The prescriber provided other rationale supporting the override.

Duration of override approval, both initial and reauthorization, to exceed the 180~~120~~-day duration of therapy limit: 12 months

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Revision	**Date**
Modify maximum duration of therapy from 120 days to 180 days, modify definition of year from fiscal year to rolling 365-days, move cerebral palsy from approval criteria to exemption diagnosis, broaden list of medicines that increase risk of GI bleed, include additional prescriber-provided rationale as approval criteria.	November 2019

Louisiana ~~Fee-for-Service~~ Medicaid
Histamine II Receptor Blockers (H_2 Antagonists)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request authorization for non-preferred agents in this therapeutic category.

~~Pharmacy claims for acute (initial treatment) dosing of H_2 antagonists for recipients 16 years of age and older will process for payment for up to 90 days duration of therapy each calendar year. Claims for recipients under 16 years of age are excluded from this edit.~~
~~For use beyond 90 days duration of therapy, an appropriate diagnosis code is required at Point-of-Sale. Refer to the Pharmacy Provider Manual for more information at https://www.lamedicaid.com/provweb1/Providermanuals/manuals/PHARMACY/PHARMACY.pdf [Pages 133-135 of the 289 page electronic pdf document].~~

Approval criteria for non-preferred agents (both initial and reauthorization): ~~)~~

- For a non-preferred agent, the following conditions apply:
  - There is no preferred alternative that is exactly the ~~exact~~ same chemical entity, formulation, strength, etc.; **AND**
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated: **OR**
  - There is a medical need for a non-preferred dosage form; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no inappropriate concomitant drug therapies or disease states.

Duration of authorization approval, both initial and reauthorization: 12 months

Duration of therapy limit for H_2 receptor blockers:

All H_2 receptor blockers are subject to a duration of therapy limit. This limit is 180 days in a rolling 365-day period (this does not apply to recipients under 16 years of age). For use beyond 180 days duration, an appropriate diagnosis code is required at Point-of-Sale (See page 2 for the list of acceptable diagnosis codes in Table 1).

Table 1. Diagnosis Codes Exempt from the Duration of Therapy Limit for H_2 Receptor Blockers

Abscess of Esophagus	K20.8
Barrett's Esophagus	K22.7*
Crohn's Disease	K50.*
Chronic Pancreatitis	K86.0, K86.1
Duodenal Ulcer	K26.*
Esophagitis, Unspecified	K20.9
Gastric Hyperacidity	K30
Gastric Ulcer	K25.*
Gastritis/Duodenitis	K29.*
Gastroesophageal Reflux Disease (GERD)	K21.9
Gastrointestinal Hemorrhage	K92.2
~~*H. pylori*~~	~~B96.81~~
Malignant Mast Cell Tumors	C96.2
Multiple Endocrine Adenomas	D44.0, D44.2, D44.9
Peptic Ulcer	K27.*
Reflux Esophagitis	K21.0
Ulcer of Esophagus with OR without Bleeding	K22.1*
Zollinger-Ellison Syndrome	E16.4

* Any number or letter or combination of **UP TO FOUR** numbers and letters of an assigned ICD-10-CM diagnosis code

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Revision	**Date**
Modify maximum duration of therapy from 90 days to 180 days, modify definition of year from calendar year to rolling 365-days, remove H. pylori from exemption diagnosis chart, combine PA criteria document with duration of therapy document	November 2019

Louisiana Medicaid
Short-Acting Narcotic Analgesics

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request authorization for non-preferred agents.

~~Acetaminophen with Codeine (Capital® and Codeine, Tylenol #3®; Tylenol #4®)~~
~~Acetaminophen with Codeine Elixir~~
~~Benzhydrocodone/Acetaminophen (Apadaz®)~~
~~Butalbital Compound with Codeine (Fiorinal with Codeine®)~~
~~Butalbital/Caffeine/Acetaminophen with Codeine~~
~~Butorphanol Tartrate Nasal~~
~~Carisoprodol Compound with Codeine~~
~~Codeine Tablet~~
~~Dihydrocodeine Bitartrate/Acetaminophen/Caffeine~~
~~Fentanyl Buccal (Fentora®)~~
~~Fentanyl Nasal Solution (Lazanda®)~~
~~Fentanyl Sublingual (Abstral®)~~
~~Fentanyl Sublingual Spray (Subsys®)~~
~~Fentanyl Transmucosal Oral Lozenge (Actiq®)~~
~~Hydrocodone with Acetaminophen Solution (Lortab®)~~
~~Hydrocodone with Acetaminophen Tablet (Lortab®; Norco®)~~
~~Hydrocodone with Ibuprofen (Ibudone®)~~
~~Hydromorphone Liquid (Dilaudid®)~~
~~Hydromorphone Suppositories; Liquid~~
~~Hydromorphone Tablet (Dilaudid®)~~
~~Levorphanol Tablet~~
~~Meperidine Solution~~
~~Meperidine Tablet~~
~~Morphine Concentrate Solution~~
~~Morphine Solution~~
~~Morphine Suppositories~~
~~Morphine, IR Tablet~~
~~Oxycodone Capsule~~
~~Oxycodone Concentrate~~
~~Oxycodone HCl Tablet (Oxaydo®)~~
~~Oxycodone Solution Syringe~~
~~Oxycodone Tablet (Roxicodone®)~~
~~Oxycodone with Acetaminophen Solution (Roxicet®)~~
~~Oxycodone with Acetaminophen Tablet (Percocet®; Primlev®)~~
~~Oxycodone with Aspirin~~
~~Oxycodone with Ibuprofen~~
~~Oxymorphone IR Tablet (Opana®)~~
~~Pentazocine with Naloxone~~
~~Tapentadol (Nucynta®)~~
~~Tramadol (Ultram®)~~
~~Tramadol with Acetaminophen (Ultracet®)~~

***ALL** narcotic analgesics have **Black Box Warnings** and are subject to **Risk Evaluation Mitigation Strategy (REMS)** under FDA safety regulations.*

Initial and Reauthorization Approval Criteria for Non-Preferred Narcotic Analgesics
(ALL of the following are required)

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- **ONE** of the following is required and is stated on the request:
  - The recipient has had *treatment failure* with at least one preferred agent; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred agent; **OR**
  - The recipient has *documented contraindication(s)* to the preferred agents that are appropriate for the condition being treated; **OR**
  - There is *no preferred agent that is appropriate* to use for the condition being treated; **OR**
  - There is a *medical need for a non-preferred dosage form*; **OR**
  - The request is to *continue established therapy* (applies to *cancer diagnosis* only), and the prescriber states on the request that the recipient is *established on the medication;* **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no inappropriate concomitant drug therapies or disease states.

Duration of Authorization Approval for Non-Preferred Short-Acting Narcotic Analgesics

Initial and reauthorization approval for cancer diagnosis: 12 months
Initial and reauthorization approval for non-cancer diagnosis for long-term care recipients: 6 months
Initial and reauthorization approval for non-cancer diagnosis: 4 months

~~**ALL narcotic analgesics have Black Box Warnings and are subject to *Risk Evaluation Mitigation Strategy* (REMS) under FDA safety regulations.**~~

~~*Additional edits may apply at Point-of-Sale (POS). Override options may be available. For more information, refer to the Louisiana Department of Health Pharmacy Benefits Management Services Manual at https://www.lamedicaid.com/provweb1/Providermanuals/manuals/PHARMACY/PHARMACY.pdf.*~~

Some narcotic analgesics have **age limits** (See Table 1).

Table 1. Age Limits for Selected Short-Acting Narcotic Analgesics

Generic (Brand Example)	Minimum Age
Codeine (in combination with any ingredient)	12
Codeine (single-ingredient)	18
Fentanyl (Lazanda®)	18
Fentanyl (Subsys®)	18
Tramadol (Ultram®)	17
Tramadol/Acetaminophen (Ultracet®)	17

Some narcotic analgesics have **diagnosis requirements** (See Table 2).

Table 2. Diagnosis Requirements for Selected Short-Acting Narcotic Analgesics

Generic (Brand Example)	Required Diagnosis (ICD-10 Code)
Fentanyl Buccal (Generic; Fentora®)	Cancer (C00*-C96*)
Fentanyl Nasal Solution (Lazanda®)	Cancer (C00*-C96*)
Fentanyl Sublingual (Abstral®)	Cancer (C00*-C96*)
Fentanyl Sublingual Spray (Subsys®)	Cancer (C00*-C96*)
Fentanyl Transmucosal Oral Lozenge (Actiq®)	Cancer (C00*-C96*)

*any number or letter or combination of **UP TO FOUR** numbers and letters of an assigned ICD-10 diagnosis code

Some short-acting narcotic analgesics have **quantity limits**. The quantity limits are based upon the recipient's recent history of opioid use. Some single-ingredient and combination products that contain the same opioid are counted together toward the quantity limit (See Table 3).
NOTE: With the exception of Abstral®, Actiq® and Fentora®, quantity limits do not apply to narcotic analgesics when prescribed for cancer, palliative end-of-life care, second and third degree burns and corrosions, and sickle-cell crisis.

Table 3. Short-Acting Narcotic Analgesic Quantity Limits Based on Previous Opioid Claims

No Opioid Claim in Previous 90-days		Opioid Claim in Previous 90-days	
Description	**7-day Quantity Limit**	**Description**	**30-day Quantity Limit**
Codeine/Acetaminophen	28 units	Codeine/Acetaminophen	Not Addressed
Benzhydrocodone/Acetaminophen	28 units	Benzhydrocodone/Acetaminophen	45 units
Fentanyl Buccal/Sublingual Lozenge/Tablet	Not Addressed	Fentanyl Buccal/Sublingual Lozenge/Tablet	120 units
Hydrocodone/Acetaminophen	28 units	Hydrocodone/Acetaminophen	45 units
Hydrocodone/Ibuprofen	28 units	Hydrocodone/Ibuprofen	30 units
Hydromorphone	28 units	Hydromorphone	45 units
Meperidine	28 units	Meperidine	45 units
Morphine	28 units	Morphine	45 units
Oxycodone	28 units	Oxycodone	45 units total
Oxycodone/Acetaminophen	28 units	Oxycodone/Acetaminophen	
Oxycodone/Aspirin	28 units	Oxycodone/Aspirin	
Oxycodone/Ibuprofen	14 units	Oxycodone/Ibuprofen	28 units
Oxymorphone	28 units	Oxymorphone	45 units
Tapentadol	28 units	Tapentadol	45 units
Tramadol	28 units	Tramadol	45 units
Tramadol/Acetaminophen	28 units	Tramadol/Acetaminophen	40 units
Oral Opioid Liquid Formulation Quantity Limits if No Opioid Claim in Previous 90 days			
All oral opioid liquid products have a quantity limit of 6 ounces (180ml) or a 7-day supply (whichever is less) if there is no opioid claim in the previous 90 days.			
Carisoprodol Quantity Limits			

All carisoprodol products (including carisoprodol with codeine) have a quantity limit of 90 tablets per rolling 90 days. The quantity limit is cumulative and applies to all strengths and combination of carisoprodol.

Table 4. Diagnosis Codes Exempt from Quantity Limits for Most Narcotic Analgesics

Diagnosis Description	Diagnosis Code
Cancer	C00*-C96*
Palliative End-of-Life Care	Z51.5
Second- or Third-Degree Burns or Corrosions	T20.2*-T20.3*, T20.6*-T20.7*, T21.2*-T21.3*, T21.6*-T21.7*, T22.2*-T22.3*, T22.6*-T22.7*, T23.2*-T23.3*, T23.6*-T23.7*, T24.2*-T24.3*, T24.6*-T24.7*, T25.2*-T25.3*, T25.6*-T25.7*
Sickle-Cell Crisis	D57.0*, D57.21*, D57.41*, D57.81*

* any number or letter or combination of **UP TO FOUR** numbers and letters of an assigned ICD-10 diagnosis code

Some narcotic analgesics have a **maximum allowed daily dose** (See Table 5).

Table 5. Maximum Daily Dose for Selected Short-Acting Narcotic Analgesics

Generic (Brand Example)	Maximum Daily Dose
Tapentadol (Nucynta®)	700mg
Tramadol (Ultram®) for Recipients < 76 years old	400mg
Tramadol (Ultram®) for Recipients > 75 years old	300mg
Tramadol/Acetaminophen (Ultracet®)	8 tablets

Additional edits may apply at Point-of-Sale (POS). Override options may be available. For more information, refer to the Louisiana Department of Health Pharmacy Benefits Management Services Manual at https://www.lamedicaid.com/provweb1/Providermanuals/manuals/PHARMACY/PHARMACY.pdf.

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Revision	Date
Added Apadaz Point-of-Sale Edits and Exemptions to Criteria	October 2019
Added Liquid Opioid Quantity Limit	November 2019

Louisiana Medicaid
Quantity Limit and Maximum Daily Morphine Milligram Equivalent (MME)
Criteria for Narcotic Analgesics

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request authorization to override maximum quantity limits **AND/OR** maximum cumulative daily morphine milligram equivalent (MME) limits.

With the exception of Abstral®, Actiq® and Fentora®, **prescriptions for recipients receiving narcotic analgesics with a diagnosis code indicating cancer, palliative end-of-life care, second and third degree burns and corrosions, or sickle-cell crisis are not subject to a quantity limit OR maximum cumulative daily MME**. *NOTE*: Even if quantity limits and/or maximum daily MME are bypassed with these diagnoses, a non-preferred product will still require prior authorization.

Table 1. Diagnosis Codes That Bypass Narcotic Analgesic Quantity Limits or Maximum Daily MME

Diagnosis Description	Diagnosis Code
Cancer	C00*-C96*
Palliative End-of-Life Care	Z51.5
Second- or Third-Degree Burns or Corrosions	T20.2*-T20.3*, T20.6*-T20.7*, T21.2*-T21.3*, T21.6*-T21.7*, T22.2*-T22.3*, T22.6*-T22.7*, T23.2*-T23.3*, T23.6*-T23.7*, T24.2*-T24.3*, T24.6*-T24.7*, T25.2*-T25.3*, T25.6*-T25.7*
Sickle-Cell Crisis	D57.0*, D57.21*, D57.41*, D57.81*

* Any number or letter or combination of **UP TO FOUR** numbers and letters of an assigned ICD-10 diagnosis code

Quantity Limits and Maximum Cumulative Daily Morphine Milligram Equivalent (MME) Limits

- Quantity limits for short-acting narcotic analgesics are based upon the recipient's recent history of opioid use and a 7-day supply. Quantity limits for long-acting narcotic analgesics are based upon a 30-day supply.
- The MME is a value assigned to each opioid to represent the potency of that opioid using morphine as the standard for comparison. For more information on MME, please visit https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf. The maximum cumulative daily MME for all concomitant opioid medications is limited to 90 MME per day.

Approval Criteria to Exceed Maximum Quantity Limit or Maximum Cumulative Daily MME:

ALL of the following are required:

- **ONE** of the following is required and is stated on the request:
  - The recipient has had a *positive response to the requested therapy* as evidenced by an improvement in function and/or signs and symptoms of pain, *without evidence of adverse effects, abuse, or dependence*; **AND**
    - The recipient *is currently taking the requested dosage and quantity*; **OR**
    - The recipient *has taken the requested dosage and quantity in the past*; **OR**
  - The recipient had a *partial but inadequate response* to the requested medication *at a lower dosage and quantity* **AND ALL** of the following:
    - Medication *non-adherence was ruled out* as a reason for the inadequate response; **AND**
    - The recipient *tolerated* the medication at *the lower dosage*; **AND**
    - There was *no evidence of adverse effects, abuse, or dependence* at the lower dose; **AND**

        - The *medication quantity and dose, as requested, are necessary for this patient*; **OR**
    - The recipient *has not previously used this medication*; however, the prescriber is *citing references* for supporting quantity limit exception with this request (for example, a peer-reviewed journal article demonstrating the safety and efficacy of the requested dose for the indication); **AND ALL** of the following:
        - The requested quantity and dosing are supported in the accepted medical compendia; **AND**
        - The *medication quantity and dose, as requested, are necessary for this patient*; **OR**
    - Concomitant narcotic analgesic therapies may **OR** may not exceed individual quantity limits, but the total daily MME exceeds the maximum cumulative daily MME limit; **AND**
        - The *recipient is currently being treated with the requested cumulative daily MME* with a *positive response to treatment* as evidenced by an improvement in function and/or signs and symptoms of pain, *without evidence of adverse effects, abuse, or dependence*; **OR**
        - The recipient is *not currently being treated with the requested cumulative daily MME*, but the addition of new therapy causes the cumulative daily MME to exceed the maximum cumulative daily MME limit, and *the requested cumulative daily MME is necessary for this patient*; **AND**
- The total daily dose of the requested medication cannot be achieved with a lower quantity of a higher strength that does not exceed the quantity limit (e.g. two 25mcg/hr patches should not be used to build a 50mcg/hr dose when a 50mcg/hr patch is available); **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no inappropriate concomitant drug therapies or disease states.

Renewal Approval Criteria to Exceed Maximum Quantity Limit or Maximum Morphine Milligram Equivalent Dose (MME) [BOTH are required]:

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber states on the request that the recipient has had a *positive response to treatment* as evidenced by an improvement in function and/or signs and symptoms of pain, *without evidence of adverse effects, abuse, or dependence*.

Duration of Authorization Approval for Override of the Quantity Limit AND/OR MME Limit

Initial and reauthorization approval for non-cancer diagnosis for long-term care recipients: 6 months
Initial and reauthorization approval for non-cancer diagnosis: 4 months

Additional edits may apply at Point-of-Sale (POS). Override options may be available. For more information, refer to the Louisiana Department of Health Pharmacy Benefits Management Services Manual at https://www.lamedicaid.com/provweb1/Providermanuals/manuals/PHARMACY/PHARMACY.pdf

Table 2. Narcotic Analgesic Quantity Limits

Short-Acting Quantity Limits by Generic			
No Opioid Claim in Previous 90 ~~-~~days		**Opioid Claim in Previous 90 ~~-~~days**	
Description	**7-day Quantity Limit**	**Description**	**30-day Quantity Limit**
Codeine/Acetaminophen	28 units	Codeine/Acetaminophen	Not Addressed
Benzhydrocodone/Acetaminophen	28 units	Benzhydrocodone/Acetaminophen	45 units
Fentanyl Buccal/Sublingual Lozenge/Tablet	Not Addressed	Fentanyl Buccal/Sublingual Lozenge/Tablet	120 units
Hydrocodone/Acetaminophen	28 units	Hydrocodone/Acetaminophen	45 units
Hydrocodone/Ibuprofen	28 units	Hydrocodone/Ibuprofen	30 units
Hydromorphone	28 units	Hydromorphone	45 units
Meperidine	28 units	Meperidine	45 units
Morphine	28 units	Morphine	45 units
Oxycodone	28 units	Oxycodone	45 units total
Oxycodone/Acetaminophen	28 units	Oxycodone/Acetaminophen	
Oxycodone/Aspirin	28 units	Oxycodone/Aspirin	
Oxycodone/Ibuprofen	14 units	Oxycodone/Ibuprofen	28 units
Oxymorphone	28 units	Oxymorphone	45 units
Tapentadol	28 units	Tapentadol	45 units
Tramadol	28 units	Tramadol	45 units
Tramadol/Acetaminophen	28 units	Tramadol/Acetaminophen	40 units
Oral Opioid Liquid Formulation Quantity Limits if No Opioid Claim in Previous 90 days			
All oral opioid liquid products have a quantity limit of 6 ounces (180ml) or a 7-day supply (whichever is less) if there is no opioid claim in the previous 90 days.			
Long-Acting 30-day Quantity Limits by Generic (Brand Example)			
Fentanyl Patch (Duragesic®) 12mcg/hr, 25mcg/hr, 37.5mcg/hr, 50mcg/hr			10 units
Fentanyl Patch (Duragesic®) 62.5mcg/hr, 75mcg/hr, 87.5mcg/hr, 100mcg/hr			20 units
Hydromorphone (Exalgo®)			30 units
Hydrocodone (Zohydro ER®)			60 units
Hydrocodone (Hysingla ER®)			30 units
Methadone			45 units
Morphine (Avinza®)			30 units
Morphine (Kadian®)			30 units
Morphine (MS Contin®)			60 units
Morphine/Naltrexone (Embeda®)			60 units
Oxycodone (Oxycontin®)			60 units
Oxycodone (Xtampza ER®)			60 units
Oxymorphone (Opana ER®)			60 units
Tapentadol (Nucynta ER®)			60 units
Tramadol ER (Conzip®)			30 units

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REMS https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm 9/18/2018 updated - includes all opioid analgesics

Revision	**Date**
Added Apadaz Point-of-Sale edits to Criteria	October 2019
Added Liquid Opioid Quantity Limit	November 2019

Louisiana ~~Fee-for-Service~~ Medicaid
Cytokine and CAM Antagonists

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical ~~pre-~~authorization for preferred and non-preferred cytokine or CAM antagonists.

~~Abatacept Injection Clickject; Syringe; Vial (Orencia®)~~
~~Adalimumab Injection Pen Kit; Syringe Kit (Humira®)*~~
~~Anakinra Injection Syringe (Kineret®)~~
~~Apremilast Tablet (Otezla®)~~
~~Baricitinib Tablet (Olumiant®)~~
~~Brodalumab Injection Syringe (Siliq®)*^~~
~~Canakinumab/PF Injection Vial (Ilaris®)~~
~~Certolizumab Pegol Injection Kit; Syringe Kit (Cimzia®)*~~
~~Etanercept Injection Kit; Mini Cartridge; Pen; Syringe (Enbrel®)*~~
~~Golimumab Injection SQ Pen; SQ Syringe; IV Vial (Simponi®, Simponi Aria®)*~~
~~Guselkumab Injection Syringe (Tremfya®)~~
~~Infliximab Injection Vial (Inflectra®*, Remicade®*, Renflexis®*)~~
~~Ixekizumab Injection Autoinjector; Syringe (Taltz®)~~
~~Rilonacept Injection Vial (Arcalyst®)~~
~~Sarilumab Injection Pen; Syringe (Kevzara®)*~~
~~Secukinumab Injection Pen; Syringe (Cosentyx®)~~
~~Tildrakizumab-asmn Injection Syringe (Ilumya®)~~
~~Tocilizumab Injection Syringe; Vial (Actemra®)*~~
~~Tofacitinib Tablet (Xeljanz®)*~~
~~Tofacitinib ER Tablet (Xeljanz® XR)*~~
~~Ustekinumab Injection Syringe; Vial (Stelara®)~~
~~Vedolizumab Injection Vial (Entyvio®)~~

~~*** These**~~*Some of these agents have* ***Black Box Warnings*** *and/or are*~~**; please refer to individual prescribing information for details.**~~

~~**^ This agent is**~~ *subject to* ***Risk Evaluation and Mitigation Strategy (REMS)*** *under FDA safety Regulations. Please*~~;~~ *refer to individual prescribing information for details.*

General approval~~Approval~~ criteria for both preferred and non-preferred cytokine and CAM antagonists (ALL criteria must be met):

- An appropriate ICD-10 diagnosis code is required, and the agent must be prescribed according to U.S. Food and Drug Administration approved indications, dosing, safety and monitoring regulations; **AND**
- By submitting the authorization request, the prescriber attests to the following:

- The ~~prescriber states on the request that the~~ recipient will not receive~~be receiving~~ the requested medication in combination with any other cytokine or CAM antagonist; **AND**
- The~~By submitting this request, the prescriber is attesting that the~~ recipient has no evidence of an active infection (including Hepatitis B virus and/or tuberculosis) within the last 180 days; **AND**
- The recipient was tested for latent tuberculosis in the past 30 days, and test results are documented in the medical record. If the recipient tested positive for latent TB, treatment for TB will begin prior to starting the requested medication; **AND**
- The recipient was tested for Hepatitis B infection within the past 30 days, and test results are documented in the medical record. If the recipient is an inactive carrier of the Hepatitis B virus (with no clinically overt liver disease), he/she will be closely monitored for reactivation of Hepatitis B infection during and after treatment with the requested drug; **AND**

~~• By submitting the authorization request, the prescriber attests to the following:~~

- The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
- All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
- The recipient has no ~~inappropriate~~ concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling; **AND**

~~•~~ For those agents identified as non-preferred on the PDL, the following conditions apply:

• ~~For those agents identified as non-preferred on the PDL, the following conditions apply and is **stated on the request**:~~

- There is no preferred alternative that is exactly the ~~exact~~ same chemical entity, formulation, strength, etc.; **AND**
- **ONE** of the following is true and is **stated on the request**
  - The recipient had documented *intolerable side effects* or a documented *treatment failure* with an adequate trial (6-12 weeks) of **TWO** preferred agents, if the preferred agents are indicated for the specified diagnosis; **OR**
  - The recipient has a *contraindications* to ~~all of~~ the preferred agents indicated for the specified diagnosis.

~~**Initial Approval: 6 months**~~
~~**Reauthorization Approval: 12 months**~~

~~**General reauthorization criteria for both preferred and non-preferred cytokine or CAM antagonists (ALLAuthorization renewed based upon the following criteria must be met):c**~~:

- ~~Recipient continues to meet initial approval criteria (general and drug/diagnosis specific);; **AND**~~
- ~~The prescriber **states on the request** that there is evidence of a positive response to treatment therapy as indicated by either maintenance of the current condition or improvement in signs and symptoms compared to baseline, or by halting of disease progression (no progression of disease signs and symptoms as compared to baseline).~~.

Approval criteria for specific diagnoses:

Ankylosing Spondylitis [for Cimzia®, this includes Non-Radiographic Axial Spondyloarthritis] (Cosentyx®, Cimzia®, Enbrel®, Humira®, Inflectra®, Remicade®, Renflexis®, Simponi®, Simponi Aria®)

- The recipient is 18 years of age or older; **AND**
- The following is true and is **stated on the request**:
  - The prescriber is (or has consulted with) a rheumatologist; **AND**
  - The recipient had documented intolerable side effects or a documented treatment failure with a non-steroidal anti-inflammatory agent (NSAID) during a single 3-month period; **OR**
  - The recipient has a contraindication to NSAIDs.

Crohn's Disease (Cimzia®, Entyvio®, Humira®, Inflectra®, Renflexis®, Remicade®, Stelara®)

- For Humira®, Inflectra®, Renflexis® or Remicade®, the recipient is 6 years of age or older; **OR**
- For Cimzia®, Entyvio®, or Stelara®, the recipient is 18 years of age or older; **AND**
- The following is true and is **stated on the request**:
  - The disease is moderate to severe (indicated by recent hospitalization, anemia requiring blood transfusion, significant weight loss, fever or malnutrition); **AND**
  - The prescriber is (or has consulted with) a gastroenterologist; **AND**
  - The recipient has a contraindication to~~, or~~ documented intolerance or treatment failure with an adequate trial (6-12 weeks) of **ONE** conventional systemic treatment for Crohn's disease~~therapy~~ which includes but is not limited to corticosteroids, 5-aminosalicylates, 6-mercaptopurine, azathioprine, or methotrexate; **AND**
  - For Entyvio®, the recipient:
    - ~~had~~ Had an inadequate response with, lost response to, or was intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; **OR**
    - ~~had~~ Had an inadequate response with, was intolerant to, or demonstrated dependence on corticosteroids; **OR**
  - For Stelara®, the recipient:

- ~~failed~~ Failed or was intolerant to treatment with immunomodulators or corticosteroids, but never failed a TNF blocker; **OR**
- ~~failed~~ Failed or was intolerant to treatment with one or more TNF blockers.

Cytokine release syndrome (CRS), severe or life-threatening (Actemra®)

- The recipient is 2 years of age or older; **AND**
- The following is true and is **stated on the request**:
  - The prescriber is (or has consulted with) a rheumatologist or an oncologist or specialist in the area of chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome; **AND**
  - Prior to the initiation of treatment with Actemra® ~~therapy~~, lab testing was performed consisting of an absolute neutrophil count (ANC), platelet count, and liver function tests (ALT/AST); **AND**
  - Adult recipients have an ANC $\geq$ 2,000/mm^3, a platelet count $\geq$ 100,000/mm^3, and the ALT/AST levels do not exceed 1.5 times the upper limit of normal (ULN); **AND**
  - Actemra® is prescribed according to U.S. Food and Drug Administration labeled dosing for CRS:
    - 12mg/kg for recipients weighing < 30kg
    - 8mg/kg for recipients weighing $\geq$ 30kg;
    - Up to a maximum of 800mg per infusion and a maximum of 4 doses up to at least 8 hours apart.

Giant cell arteritis (Actemra®)

- The recipient is 18 years of age or older; **AND**
- The following is true and is **stated on the request**:
  - Prior to the initiation of treatment with Actemra® ~~therapy~~, lab testing was performed consisting of an ANC, platelet count, and liver function tests (ALT/AST); **AND**
  - The recipient has an ANC $\geq$ 2,000/mm^3, a platelet count $\geq$ 100,000/mm^3, and the ALT/AST levels do not exceed 1.5 times the upper limit of normal (ULN); **AND**
  - The recipient had an inadequate response to systemic corticosteroids (e.g., prednisone).

Hidradenitis Suppurativa (Humira®)

- The recipient is 12 years of age or older; **AND**
- The following is true and is **stated on the request**:
  - The recipient has a diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III); **AND**
  - The prescriber is (or has consulted with) a dermatologist; **AND**
  - For Hurley stage II disease, the recipient had an inadequate response to conventional treatment for Hidradenitis Suppurativa~~therapy~~, which may include, but is not limited to, oral tetracyclines, oral retinoids, and hormonal therapy.

~~**Systemic Juvenile Idiopathic Arthritis (Actemra®, Ilaris®)**~~

- ~~The recipient is 2 years of age or older; **AND**~~
- ~~The following is true and is stated on the request:~~
  - ~~The prescriber is (or has consulted with) a rheumatologist; **AND**~~
  - ~~For Ilaris®, the maximum dose is 300mg every 4 weeks administered subcutaneously; **AND**~~
  - ~~The recipient has a contraindication to or documented intolerance or failure with an adequate trial (6-12 weeks) of **AT LEAST ONE** disease modifying antirheumatic drug (DMARD) (such as methotrexate, corticosteroids, or azathioprine).~~

Oral Ulcers Associated with Behçet's Disease (Otezla®)

- The recipient is 18 years of age or older; **AND**
- The recipient has a diagnosis of Behçet's Disease; **AND**
- The request states that the recipient has active oral ulcers.

Periodic Fever Syndromes:

- **Cryopyrin-Associated Periodic Syndromes (CAPS) (Kineret®, Arcalyst® and Ilaris®) -** The following is true and is **stated on the request**:
  - For Kineret®:
    - The medication is being prescribed for the treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID), which has been confirmed by one of the following:
      - NLRP-3 [nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3] gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation; **OR**
      - Evidence of active inflammation which includes both clinical symptoms (e.g., rash, fever, arthralgia) and elevated acute phase reactants (e.g., ESR, CRP); **AND**
    - The prescriber is (or has consulted with) a rheumatologist or a specialist in the treatment of NOMID; **OR**
  - For Arcalyst® and Ilaris®:
    - The medication is being prescribed for the treatment of either Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS); **AND**
    - The prescriber is (or has consulted with) a rheumatologist or a specialist in the treatment of FCAS and MWS; **AND**
  - For Arcalyst®:
    - The recipient is 12 years of age or older; **OR**
  - For Ilaris®:
    - The recipient is 4 years of age or older; **AND**
    - The maximum dose is 150mg every 8 weeks.

- **Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS); OR Hyperimmunoglobulin D Syndrome (HIDS); OR Mevalonate Kinase Deficiency (MKD); OR Familial Mediterranean Fever (FMF) (Ilaris®)**
  - The recipient is 2 years of age or older; **AND**

- The maximum dose is 300mg every 4 weeks.

Plaque Psoriasis (Cimzia®, Cosentyx®, Enbrel®, Humira®, Ilumya®, Inflectra®, Otezla®, Remicade®, Renflexis®, Siliq®, Stelara®, Taltz® and Tremfya®)

- For Cimzia®, Cosentyx®, Humira®, Ilumya®, Inflectra®, Otezla®, Remicade®, Renflexis®, Siliq®, Taltz®, or Tremfya®, the recipient is 18 years of age or older; **OR**
- For Stelara®, the recipient is 12 years of age or older; **OR**
- For Enbrel®, the recipient is 4 years of age or older; **AND**
- The following is true and is **stated on the request**:
  - ~~For Cimzia®, Cosentyx®, Enbrel®, Humira®, Otezla®, Siliq®, Stelara®, Tremfya® or Taltz®, the disease is chronic moderate to severe plaque psoriasis; **OR**~~
  - ~~For Ilumya®, the recipient has a diagnosis of moderate-to-severe plaque psoriasis; **OR**~~
  - ~~For Inflectra®, Remicade® or Renflexis®, the disease is chronic severe plaque psoriasis; **AND**~~
  - The prescriber is (or has consulted with) a rheumatologist or dermatologist; **AND**
  - ~~The recipient has Body Surface Area (BSA) involvement of at least 3% or involvement of the palms, soles, head and neck or genitalia, causing disruption in normal activities and/or employment; **AND**~~
  - The recipient has a contraindication to, ~~or~~ documented intolerance or treatment failure with an adequate trial (6-12 weeks) of **AT LEAST ONE** of the following therapies: phototherapy, methotrexate, and/or cyclosporine; **AND**
  - The recipient has Body Surface Area (BSA) involvement of at least 3% or involvement of the palms, soles, head and neck or genitalia, causing disruption in normal activities and/or employment; **AND**
  - For Cimzia®, Cosentyx®, Enbrel®, Humira®, Otezla®, Siliq®, Stelara®, Tremfya® or Taltz®, the disease is chronic moderate to severe plaque psoriasis; **OR**
  - For Ilumya®, the recipient has a diagnosis of moderate-to-severe plaque psoriasis; **OR**
  - For Inflectra®, Remicade® or Renflexis®, the disease is chronic severe plaque psoriasis; ~~**AND**~~**OR**
  - For Siliq®, the following criteria must be met:
    - ~~The recipient has signed the Siliq recipient-prescriber agreement form; **AND**~~
    - ~~The recipient has at least 10% or more of the body surface area (BSA) or 5% or more of BSA if psoriasis involves sensitive areas (hands, feet, face, or genitals); **AND**~~
    - ~~All approval criteria for the REMS (Risk Evaluation and Mitigation Strategy) program have been met; **AND**~~

- The recipient has tried at least one traditional systemic agent for psoriasis (e.g., methotrexate, cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light) for at least 3 months, (unless intolerant); **OR**
- The recipient has a contraindication to, ~~or~~ documented intolerance or treatment failure with an adequate trial (3 months) of a non-biologic agent indicated for psoriasis; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The recipient does not have Crohn's Disease; **AND**
  - The recipient has signed the Siliq recipient-prescriber agreement form; **AND**
  - All approval criteria for the REMS (Risk Evaluation and Mitigation Strategy) program have been met.
- ~~The recipient does not have Crohn's Disease.~~

Polyarticular Juvenile Idiopathic Arthritis (Actemra®, Enbrel®, Humira®, Orencia®)

- The recipient is 2 years of age or older; **AND**
- The following is true and is **stated on the request**:
  - The prescriber is (or has consulted with) a rheumatologist; **AND**
  - The recipient has a contraindication to, ~~or~~ documented intolerance or treatment failure with an adequate trial (6-12 weeks) of methotrexate or corticosteroids.

Psoriatic Arthritis (Cimzia®, Cosentyx®, Enbrel®, Humira®, Inflectra®, Orencia®, Otezla®, Remicade®, Renflexis®, Simponi®, Simponi Aria®, Stelara®, Taltz®, Xeljanz® and Xeljanz® XR)

- The recipient is 18 years of age or older; **AND**
- The following is true and is **stated on the request**:
  - The prescriber is (or has consulted with) a dermatologist or rheumatologist; **AND**
  - The recipient has a contraindication to, ~~or~~ documented intolerance or treatment failure with an adequate trial (6-12 weeks) of at least one non-biologic DMARD (such as methotrexate or leflunomide); **AND**
  - For Xeljanz® and Xeljanz® XR:
    - The agent is not being given in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine; **AND**
    - The recipient has an absolute lymphocyte count (ALC) $\geq$ 500 cells/mm^3, an ANC $\geq$ 1,000 cells/mm^3, and hemoglobin level $\geq$ 9 g/dL.

Rheumatoid Arthritis (Actemra®, Cimzia®, Enbrel®, Humira®, Inflectra®, Kevzara®, Kineret®, Olumiant®, Orencia®, Remicade®, Renflexis®, Simponi®, Simponi Aria®, Xeljanz® and Xeljanz® XR)

- The recipient is 18 years of age or older; **AND**
- The following is true and is **stated on the request**:
  - The prescriber is (or has consulted with) a rheumatologist; **AND**
  - The recipient has a contraindication to, documented intolerance or treatment failure with an adequate trial (6-12 weeks) of at least one non-biologic DMARD (such as methotrexate, leflunomide, or azathioprine); **AND**

- The agent is being used to treat moderately to severely active rheumatoid arthritis; **AND**
- For Actemra®, the dose does not exceed 800mg per infusion; **OR**
- ~~For Kineret® or Orencia®, the medication will not be given concurrently with TNF antagonists (e.g., adalimumab, certolizumab pegol, etanercept, golimumab or infliximab); **OR**~~
- For Xeljanz® and Xeljanz® XR:
  - The agent is not being given in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine; **AND**
  - The recipient has an ALC ≥ 500 cells/mm^3, an ANC ≥ 1,000 cells/mm^3, and hemoglobin level ≥ 9 g/dL; **OR**
- For Inflectra®, Remicade®, Renflexis®, Simponi® Aria, or Simponi®, the medication is being used in combination with methotrexate; **OR**
- For Kevzara®, the recipient has an ANC ≥ 2000/mm^3, a platelet count ≥150,000/mm^3 and liver transaminases do not exceed 1.5 times the upper limit of normal (ULN); **OR**
- For Olumiant®:
  - The recipient has had an inadequate response to one or more TNF antagonists (e.g., adalimumab, certolizumab pegol, etanercept, golimumab or infliximab); **AND**
  - The agent is not being given in combination with other JAK inhibitors (e.g., tofacitinib), biologic DMARDS, or with potent immunosuppressants such as azathioprine and cyclosporine; **AND**
  - The recipient has an ANC ≥ 1000/mm^3, an ALC ≥ 500/mm^3, and hemoglobin ≥ 8 g/dL.

Systemic Juvenile Idiopathic Arthritis (Actemra®, Ilaris®)

- The recipient is 2 years of age or older; **AND**
- The following is true and is stated on the request:
  - The prescriber is (or has consulted with) a rheumatologist; **AND**
  - For Ilaris®, the maximum dose is 300mg every 4 weeks administered subcutaneously; **AND**
  - The recipient has a contraindication to or documented intolerance or failure with an adequate trial (6-12 weeks) of **AT LEAST ONE** disease modifying antirheumatic drug (DMARD) (such as methotrexate, corticosteroids, or azathioprine).

Ulcerative Colitis (Entyvio®, Humira®, Inflectra®, Remicade®, Renflexis®, Simponi®, Xeljanz® and Xeljanz® XR)

- For Entyvio®, Humira®, ~~Inflectra®, Renflexis®,~~ Simponi®, Xeljanz® or Xeljanz® XR the recipient is 18 years of age or older; **OR**
- For Inflectra®, Remicade® or Renflexis®, the recipient is 6 years of age or older; **AND**
- The following is true and is **stated on the request**:
  - The disease is moderate to severe (indicated by recent hospitalization, anemia requiring blood transfusion, significant weight loss, fever or malnutrition); **AND**
  - The prescriber is (or has consulted with) a gastroenterologist; **AND**

- The recipient has a contraindication to , ~~or had~~ documented intolerance or treatment failure with an adequate trial (6-12 weeks) of **AT LEAST ONE** conventional treatment for ulcerative colitis~~therapy~~ which may include but is not limited to 6-mercaptopurine, corticosteroids (such as prednisone or methylprednisolone), or azathioprine; **AND**
- For Entyvio®, the recipient had an inadequate response with, lost response to, or was intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, was intolerant to, or demonstrated dependence on corticosteroids; **AND**
- For Xeljanz® and Xeljanz® XR:
  - The agent is not being given in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine; **AND**
  - The recipient has an ALC ≥ 500 cells/mm3, an ANC ≥ 1,000 cells/mm3, and hemoglobin level ≥ 9 g/dL.

Uveitis (Humira®)

- The recipient has a diagnosis of non-infectious intermediate, posterior, and panuveitis; **AND**
- The recipient is 2 years of age or older; **AND**
- The following is true and is **stated on the request**:
  - The prescriber is (or has consulted with) an ophthalmologist or a rheumatologist; **AND**
  - The recipient had an inadequate response to conventional treatment for uveitis~~therapy~~, which may include antibiotics, antiviral medications, or corticosteroids.

General reauthorization criteria for both preferred and non-preferred cytokine or CAM antagonists (ALL criteria must be met):

- Recipient continues to meet initial approval criteria (general and drug/diagnosis specific); **AND**
- The prescriber **states on the request** that there is evidence of a positive response to treatment as indicated by improvement in signs and symptoms compared to baseline, or by halting of disease progression (no progression of disease signs and symptoms as compared to baseline).

Initial Approval: 6 months
Reauthorization Approval: 12 months

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Revision	Date
Remove diagnosis requirement at Point-of-Sale, add Non-Radiographic Axial Spondyloarthritis for Cimzia, add max dose for Actemra for RA, add severity to RA criteria.	August 2019
Incorporate Otezla new indication for Oral Ulcers Associated with Behçet's Disease, modify age for Ulcerative Colitis for Inflectra and Renflexis.	November 2019

Louisiana ~~Fee-for-Service~~ Medicaid
Tezacaftor/Ivacaftor (Symdeko~~™)~~ ®)

~~Tezacaftor/ivacaftor (Symdeko™) ®) requires clinical authorization.~~ The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request authorization for tezacaftor/ivacaftor (Symdeko~~™).~~®).

Requests will be considered for approval if all of the following criteria are met:

- Recipient is ~~12~~ 6 years of age or older; **AND**
- Recipient has a diagnosis of cystic fibrosis (CF) and **ONE** of the following is documented on the request:
    a. The recipient is homozygous for the *F508del* mutation; **OR**
    b. The recipient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on *in vitro* data or clinical evidence.

The following mutations in the CFTR gene are responsive to tezacaftor/ivacaftor:

A1067T	A455E	D110E	D110H	D1152H	D1270N	D579G	E193K
E56K	E831X	F1052V	F1074L	K1060T	L206W	P67L	R1070W
R117C	R347H	R352Q	R74W	S945L	S977F	F508del (2 copies)	
2789+5G→A		3272-26A→G		3849+10kbC→T		711+3A→G	

Requests to continue treatment with tezacaftor/ivacaftor will be considered for approval if all of the following criteria are met:

- All of the initial request criteria are met; **AND**
- The prescriber attests that the patient has achieved a clinically significant response while on tezacaftor/ivacaftor.

Duration of authorization approval, both initial and reauthorization: 12 months

Reference

Symdeko~~™~~ (tezacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc; ~~2018~~2019. Retrieved from https://pi.vrtx.com/files/uspi_tezacaftor_ivacaftor.pdf

Louisiana Medicaid
CGRP (Calcitonin Gene-Related Peptide) Antagonists

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request authorization for CGRP (Calcitonin Gene-Related Peptide) antagonists.

Requests will be considered for initial approval if all of the following criteria are met:

- The recipient is 18 years of age or older on the date of the request; **AND**
- The requested medication ~~is being~~ has been prescribed by, or in consultation with, a neurologist or pain specialist; **AND**
- The recipient has been evaluated and does not have medication overuse headache; **AND**
- The dosage and administration follows prescribing information for the diagnosis being treated; **AND**
- For ~~any~~ ALL CGRP Antagonists, **the following is true and stated on the request**:
  - The patient has a diagnosis based on documented history of **ONE** of the following:
    - episodic migraine <15 headache days per month; **OR**
    - chronic migraine ≥15 headache days per month; **AND**
  - The patient has a history of migraines for at least 3 months; **AND**
  - The patient ~~has~~ failed ~~a 3-month trial (each)~~ treatment with an adequate trial (3 months each) of at least ~~two~~ **TWO** standard prophylactic pharmacologic therapies for migraine, or has an intolerance or contraindication to standard prophylactic therapies (e.g., beta blockers, antidepressants, divalproex sodium or topiramate); ~~**AND**~~**OR**
- For galcanezumab-gnlm (Emgality™), **the following is true and is stated on the request**:
  - The recipient has a diagnosis based on documented history of episodic cluster headaches; **AND**
  - The recipient is in an active cluster period; **AND**
  - The recipient has failed treatment with **AT LEAST** ~~**TWO**~~**ONE** triptan~~s~~ indicated for the treatment of cluster headaches (unless contraindicated); **AND**
- If the request is for a non-preferred agent - **ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has a *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of CGRP antagonists and will not ~~be receiving~~ receive CGRP antagonists in combination with any medication that is contraindicated or not recommended per FDA labeling.

Requests to continue treatment with CGRP antagonists will be considered for approval if all of the following criteria are met:

- The recipient continues to meet initial criteria; **AND**
- The following **is true and stated on the request**:
  - The recipient continues to be monitored for medication overuse headache; **AND**
  - There is documentation of a positive clinical response to CGRP antagonist therapy.

Duration of initial and reauthorization approval: 12 months

Point-of-Sale Quantity Limits for CGRP Antagonists

Medication	Quantity
erenumab-aooe (*Aimovig*®) 70mg, 140mg single-dose syringe	3 single-dose syringe/90days
fremanezumab-vfrm (*Ajovy*®) 225mg single-dose syringe	3 (225mg) single-dose syringe/90 days
galcanezumab-gnlm (*Emgality*™) 100 mg single-dose pen/syringe~~erenumab-aooe (*Aimovig*®) 70mg, 140mg single-dose syringe~~	3 single-dose syringes/30 days~~3 single-dose syringe/90days~~
galcanezumab-gnlim (*Emgality*™) 120 mg single-dose pen/syringe	7 single-dose syringes/180 days
~~galcanezumab-gnlim (*Emgality*™) 100 mg single-dose pen/syringe~~	~~3 single-dose syringes/30 days~~

References:

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Ajovy (fremanezumab-vfrm) [prescribing information]. North Wales, PA: Teva Pharmaceuticals; 2019. Retrieved from https://www.ajovyhcp.com/globalassets/ajovy/ajovy-pi.pdf

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ICHD-3.org. (2019). [online] Available at: https://ichd-3.org/wp-content/uploads/2018/01/The-International-Classification-of-Headache-Disorders-3rd-Edition-2018.pdf [Accessed 26 Jun. 2019].

Revision	Date
Added wording for new indication, strength and quantity limit for Emgality	November 2019

Louisiana Medicaid
Dupilumab (Dupixent®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for dupilumab (Dupixent®).

General approval criteria for dupilumab

- Previous use of a preferred product - **ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- The requested dose and dosing frequency are appropriate for the recipient's age, weight and diagnosis based on the prescribing information; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of dupilumab; **AND**
- The recipient meets applicable diagnosis-specific criteria below.

Approval Criteria for Specific Diagnoses

Atopic Dermatitis

- The recipient is 12 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of moderate to severe atopic dermatitis.

Moderate to Severe Asthma with an Eosinophilic Phenotype

- The recipient is 12 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype; **AND**
- The recipient is using Dupixent (dupilumab) as an add-on maintenance treatment in combination with other controller medications (e.g., inhaled corticosteroids (ICS), long-acting beta-agonists (LABA), combination ICS/LABA; leukotriene modifiers); **AND**
- By submitting the request, the prescriber attests that the recipient has been adherent to controller medication therapy, using proper inhaler technique (if applicable) and has had an inadequate response.

Chronic Rhinosinusitis with Nasal Polyposis

- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of chronic rhinosinusitis with nasal polyposis; **AND**
- The recipient is using Dupixent (dupilumab) as an add-on maintenance treatment in combination with other controller medications (e.g., intranasal corticosteroids); **AND**
- By submitting the request, the prescriber attests that the recipient has been adherent to controller medication therapy, using proper technique (if applicable) and has had an inadequate response.

Reauthorization Criteria

- The recipient continues to meet initial criteria; **AND**
- The prescriber states on the request that there is evidence of a positive response to therapy as indicated by improvement in signs, symptoms, and/or lab results compared to baseline.

Duration of authorization approval, both initial and reauthorization: 12 months

Reference

Dupixent (dupilumab) [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC *and* Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; 2019. Retrieved from https://d1egnxy4jx1q3f.cloudfront.net/Regeneron/Dupixent_FPI.pdf

Louisiana Medicaid
Mecasermin (Increlex®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for mecasermin (Increlex®).

Approval criteria for initial requests for mecasermin

- The recipient is at least 2 years of age, but not older than 18 years of age on the date of the request; **AND**
- The recipient has **ONE** of the following diagnoses **stated on the request**:
    - Growth failure with a diagnosis of severe primary insulin-like growth factor deficiency (PIGFD) as defined by:
        - Height more than three standard deviations below the mean for age; **AND**
        - IGF-1 level more than three standard deviations below the mean for age; **OR**
    - Growth hormone (GH) gene deletion and has developed neutralizing antibodies to GH; **AND**
- Mecasermin is being prescribed by, or **the request states** that mecasermin is being prescribed in consultation with, an endocrinologist; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - The recipient has open epiphyses and has not reached full adult height; **AND**
    - The recipient does not have any active or suspected malignancy; **AND**
    - The prescriber has educated the patient and/or caregiver on:
        - How to recognize the signs and symptoms of hypoglycemia; **AND**
        - How to recognize the signs and symptoms of serious allergic reactions and the need to seek prompt medical contact should such a reaction occur; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of mecasermin.

Reauthorization Criteria:

- Recipient continues to meet initial approval criteria; **AND**
- Prescriber **states on the request** that there is evidence of a positive response to therapy as indicated by improvement in signs, symptoms, and/or lab results compared to baseline.

Duration of authorization approval, both initial and reauthorization: 12 months

Reference

Increlex (mecasermin) [package insert]. McPherson, KS: Hospira, Incorporated; 2019. Retrieved from https://www.ipsen.com/websites/Ipsen_Online/wp-content/uploads/sites/9/2019/01/21153952/Increlex_Full_Prescribing_Information1.pdf

Louisiana Medicaid
Sapropterin Dihydrochloride (Kuvan®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for sapropterin dihydrochloride (Kuvan®).

Approval criteria for requests to <u>initiate</u> treatment

- The recipient is at least 1 month of age on the date of the request; **AND**
- The recipient has a diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive phenylketonuria (PKU); **AND**
- The recipient is following a phenylalanine- (Phe-) restricted diet; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - Sapropterin dihydrochloride (Kuvan®)is prescribed by, or in consultation with, a healthcare provider experienced in the management of PKU; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of sapropterin dihydrochloride.

<u>Reauthorization</u> or <u>Continuation</u> Criteria for <u>responders</u> to sapropterin dihydrochloride:

- The recipient continues to meet initial approval criteria; **AND**
- The recipient's blood Phe has decreased from baseline, and this is **stated on the request.**

Duration of authorization approval when <u>initiating</u> treatment or <u>increasing</u> dosage to determine response to therapy: 2 months

Duration of reauthorization or continuation approval after response to therapy has been determined: 12 months

Reference

Kuvan (sapropterin dihydrochloride) [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; 2016. Retrieved from https://www.kuvan.com/hcp/wp-content/file/KUVAN_Prescribing_Information1.pdf

Louisiana Medicaid
Sodium Zirconium Cyclosilicate (Lokelma™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for sodium zirconium cyclosilicate (Lokelma™).

Approval criteria for requests to <u>initiate</u> treatment

- The recipient is at least 18 years of age on the date of the request; **AND**
- The recipient has a diagnosis of non-life-threatening hyperkalemia; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - Sodium zirconium cyclosilicate will **NOT** be used as an emergency treatment for life threatening hyperkalemia because of its delayed onset of action; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of sodium zirconium cyclosilicate.

Reauthorization or Continuation Criteria:

- The recipient continues to meet initial approval criteria; **OR**
- The prescriber states on the request that the recipient is established on sodium zirconium cyclosilicate therapy and that there has been a positive clinical response.

Duration of authorization approval, both initial and reauthorization: 12 months

Reference

Lokelma (sodium zirconium cyclosilicate) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2018. Retrieved from https://www.azpicentral.com/lokelma/lokelma.pdf#page=1

Louisiana Medicaid
Cladribine (Mavenclad®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for cladribine (Mavenclad®).

*Cladribine (Mavenclad®) has a **Black Box Warning**. Please refer to prescribing information for details.*

Approval criteria for requests to initiate treatment

- The recipient is 18 years of age or older on the date of the request; **AND**
- Cladribine (Mavenclad®) is being prescribed by, or the request states cladribine (Mavenclad®) is being prescribed in consultation with, a neurologist; **AND**
- The recipient has been diagnosed with a relapsing form of multiple sclerosis (ICD-10 code G35), to include relapsing-remitting disease or active secondary progressive disease; **AND**
- **ONE** of the following applies:
    - The recipient has had a *treatment failure* with at least **TWO** multiple sclerosis agents [at least **ONE** must be preferred] (See Multiple Sclerosis – Immunomodulatory Agents on PDL); **OR**
    - The recipient has had an *intolerable side effect* with at least **TWO** multiple sclerosis agents [at least **ONE** must be preferred] (See Multiple Sclerosis – Immunomodulatory Agents on PDL); **OR**
    - The recipient has *documented contraindication(s)* to **ALL** multiple sclerosis agents that are appropriate to use for the condition being treated (See Multiple Sclerosis – Immunomodulatory Agents on PDL); **OR**
    - There are *no multiple sclerosis agents that are appropriate for the condition* being treated (See Multiple Sclerosis – Immunomodulatory Agents on PDL); **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescriber has advised all patients of reproductive potential to use effective contraception during cladribine dosing and for 6 months after the last dose in each treatment course; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of cladribine (Mavenclad®).

Reauthorization Criteria

- The recipient continues to meet all initial approval criteria; **AND**
- By submitting the reauthorization request, the prescriber attests that:
    - At least 43 weeks have passed since the last dose of the second cycle of the first course of cladribine (Mavenclad®) treatment; **AND**
    - At least 2 years have passed since the last dose of the second cycle of the second course of cladribine (Mavenclad®) treatment.

Duration of initial or reauthorization approval: 32 days

References:

Mavenclad® (cladribine) [package insert]. Rockland, MA: EMD Serono, Inc; 2019. Retrieved from https://www.mavenclad.com/content/dam/web/healthcare/neurology/united-states/pdfs/Prescribing%20Information.pdf

Louisiana ~~Fee-for-Service~~ Medicaid
Multiple Sclerosis Agents

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for ~~all multiple sclerosis agents listed on the Preferred Drug List (PDL)/Prior Authorization (PA) List,~~ preferred and non-preferred multiple sclerosis agents.

~~*~~ *~~T~~Some of these agents have **Black Box~~ed~~ Warnings~~:~~ and some of these agents are subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety Regulations. ~~P~~Please refer to individual prescribing information for details.*

~~^ These agents are subject to Risk Evaluation and Mitigation Strategy (REMS) under FDA safety Regulations; please refer to prescribing information for details.~~

Approval criteria for ~~all agents:~~specific diagnoses

Multiple Sclerosis

- The medication is being prescribed by or in consultation with a neurologist; **AND**
- ~~•~~ The recipient has a diagnosis of ~~:~~
  - ~~o Moderately-to-severely active Crohn's disease (ICD-10 code K50*) if the requested medication is Tysabri®; **OR**~~
  - ~~•~~ ~~M~~multiple sclerosis (ICD-10 code G35); **AND**
- **ONE** of the following applies:
  - The request is for a preferred medication; **OR**
  - The request is for a non-preferred medication; **AND**
    - **ONE** of the following applies:
      - There is no preferred product that is ~~that does **NOT HAVE** a chemically equivalent preferred product of~~ the exact same chemical entity, formulation, strength, etc.; ~~**AND**~~**OR**
    - ~~The prescriber states on the request that the recipient is currently using the medication *(current use of the requested medication is not established through use of medication samples, coupons or discount cards)*; **OR**~~
    - ~~The recipient has had a *treatment failure* with at least one preferred product; **OR**~~
    - ~~The recipient has had an *intolerable side effect* to at least one preferred product; **OR**~~
    - ~~The recipient has *documented contraindication(s)* to the preferred products that are appropriate to use for the condition being treated; **OR**~~
    - ~~There is *no preferred product appropriate for the condition* being treated; **OR**~~
  - ~~The request is for a non-preferred medication that **DOES HAVE** a chemically equivalent preferred product of the exact same entity, formulation, strength, etc.; **AND**~~
    - ~~For the chemically equivalent preferred product(s):~~
      - The following is true and is **stated on the request** – ~~There is documentation in the recipient's medical record stating that t~~The recipient is unable to use the chemically equivalent preferred product for reasons such as a contraindication or clinically significant adverse effect(s) to ~~the~~ an inactive ingredient~~(s)~~ that it contains; **AND**
    - ~~For all other preferred products which are not chemically equivalent to the requested non-preferred product~~**ONE** of the following applies:

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- The prescriber **states on the request** that the recipient is currently using the medication *(current use of the requested medication is not established through use of medication samples, coupons or discount cards)*; **OR**
- The recipient has had a *treatment failure* with at least one preferred product that is indicated for treatment of multiple sclerosis; **OR**
- The recipient has had an *intolerable side effect* to at least one preferred product that is indicated for treatment of multiple sclerosis; **OR**
- The recipient has a *documented contraindication(s)* to all the preferred products that are appropriate to use for the condition being treated; **OR**
- There is *no preferred product that is appropriate to use for the condition* being treated; **AND**

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- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no ~~inappropriate~~ concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Crohn's Disease

- The request is for natalizumab (Tysabri®); **AND**
- The medication is being prescribed by or in consultation with a gastroenterologist; **AND**
- **ONE** of the following applies:
  - The prescriber **states on the request** that the recipient is currently using the medication *(current use of the requested medication is not established through use of medication samples, coupons or discount cards)*; **OR**
  - The recipient has had a *treatment failure* with at least one preferred product that is indicated for treatment of Crohn's disease (see Pain Management – Cytokine and CAM Antagonists on PDL); **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product that is indicated for treatment of Crohn's disease (see Pain Management – Cytokine and CAM Antagonists on PDL); **OR**
  - The recipient has a *documented contraindication(s)* to all the preferred products that are indicated for treatment of Crohn's disease (see Pain Management – Cytokine and CAM Antagonists on PDL); **OR**
  - There is *no preferred product that is appropriate to use for the condition* being treated (see Pain Management – Cytokine and CAM Antagonists on PDL); **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS),

contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**

- All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Renewal Criteria

- The recipient continues to meet all initial approval criteria; **AND**
- The prescriber states on the request that the recipient is responding positively to ~~therapy~~treatment; **AND**
- If the renewal request is for Ampyra®, the prescriber states that the patient's walking has improved with Ampyra® ~~therapy~~treatment; **OR**
- If the renewal request is for Lemtrada®:
  - It has been at least 12 months since completion of the most recent treatment course; **AND**
  - The duration of treatment for the renewal is 3 consecutive days.

Duration of initial approval: 12 months (or a 5-day treatment course for Lemtrada®)

Duration of renewal approval: 12 months (or a 3-day treatment course for Lemtrada®)

References:

Ampyra (dalfampridine) [package insert]. Ardsley, NY: Acorda Therapeutics, Inc; September 2017. ~~Retrieved from~~ https://ampyra.com/prescribing-information.pdf [**Black Box Warning**]

Aubagio (teriflunomide) [package insert]. Cambridge, MA: Genzyme Corpor~~t~~ation, A Sanofi Company; July ~~2016~~2019. ~~Retrieved from~~ http://products.sanofi.us/Aubagio/aubagio.html, ~~http://products.sanofi.us/Aubagio/Aubagio.pdf~~ [**Black Box Warning**]

Avonex (interferon beta-1a) [package insert]. Cambridge, MA: Biogen Inc; July ~~2016~~2019. ~~Retrieved from~~ https://www.avonex.com/content/dam/commercial/multiple-sclerosis/avonex/pat/en_us/pdf/Avonex_US_Prescribing_Information.pdf~~https://www.avonex.com/content/dam/commercial/multiple-sclerosis/avonex/pat/en_us/pdf/Avonex%20US%20%20Prescribing%20Information.pdf~~

Betaseron (interferon beta-1b) [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; August ~~2016~~2019. ~~Retrieved from~~ https://labeling.bayerhealthcare.com/html/products/pi/Betaseron_PI.pdf

Copaxone (glatiramer acetate) [package insert]. Overland Park, KS: Teva Pharmaceuticals USA, Inc; July ~~2018~~2019. ~~Retrieved from~~ https://www.copaxone.com/globalassets/copaxone/prescribing-information.pdf~~https://www.copaxone.com/Resources/pdfs/PrescribingInformation.pdf~~

Extavia (interferon beta-1b) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December ~~2016~~2018. ~~Retrieved from~~ https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/extavia.pdf

Gilenya (fingolimod) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January ~~2018~~2019. ~~Retrieved from~~ https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/gilenya.pdf

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Glatopa (glatiramer acetate) [package insert]. Princeton, NJ: Sandoz Inc; July ~~2018~~2019. ~~Retrieved from~~ https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=5f01e40a-b6f6-40fb-b37c-3d06f1428e86&type=display

Lemtrada (alemtuzumab) [package insert]. Cambridge, MA: Genzyme Corporation; July ~~2017~~2019. ~~Retrieved from~~ http://products.sanofi.us/lemtrada/lemtrada.html [**Black Box Warning**]

Ocrevus (ocrelizumab) [package insert]. South San Francisco, CA: Genentech, Inc; July ~~2017~~2019. ~~Retrieved from~~ https://www.gene.com/download/pdf/ocrevus_prescribing.pdf

Plegridy (peginterferon beta-1a) [package insert]. Cambridge, MA: Biogen Inc; July ~~2016~~2019. ~~Retrieved from~~ https://www.plegridyhcp.com/content/dam/commercial/multiple-sclerosis/plegridy/hcp/en_us/home/pdf/prescribing-information.pdf

Rebif (interferon beta-1a) [package insert]. Rockland, MA: EMD Serono, Inc; July ~~2015~~2019. ~~Retrieved from~~ https://www.emdserono.com/content/dam/web/corporate/non-images/country-specifics/us/pi/rebif-pi.pdf

Tecfidera (dimethyl fumarate) [package insert]. Cambridge, MA: Biogen Inc; July ~~2017~~2019. ~~Retrieved from~~ https://www.tecfiderahcp.com/content/dam/commercial/multiple-sclerosis/tecfidera/hcp/en_us/pdf/Tecfidera_PI.pdf

Tysabri (natalizumab) [package insert]. Cambridge, MA: Biogen Inc; August ~~2018~~2019. ~~Retrieved from~~ https://www.tysabrihcp.com/content/dam/commercial/multiple-sclerosis/tysabri/hcp/en_us/PDFs/tysabri_prescribing_information.pdf [**Black Box Warning**]

Medication	DX Code	Indication
HIV Agents	B16.1	Acute hepatitis B with delta-agent without hepatic coma
	B16.2	Acute hepatitis B without delta-agent with hepatic coma
	B16.9	Acute hepatitis B w/o delta-agent and without hepatic coma
	B18.0	Chronic viral hepatitis B with delta-agent
	B18.1	Chronic viral hepatitis B without delta-agent
	B19.1	Unspecified viral hepatitis B
	B19.10	Unspecified viral hepatitis B without hepatic coma
	B19.11	Unspecified viral hepatitis B with hepatic coma
	B20	Human immunodeficiency virus [HIV] disease
	B97.35	Human immunodeficiency virus, type 2 [HIV 2] as the cause of diseases classified elsewhere
	W46.0XXA	Contact with hypodermic needle (initial enc.)
	W46.0XXD	Contact with hypodermic needle (subsequent enc.)
	W46.1XXA	Contact with contaminated hypodermic needle (initial enc.)
	W46.1XXD	Contact with contaminated hypodermic needle (subsequent enc.)
	Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
	Z20.6	Contact with and (suspected) exposure to HIV
	Z20.828	Contact with and (suspected) exposure to other viral communicable diseases
	Z20.89	Contact with and (suspected) exposure to other communicable diseases
	Z20.9	Contact with and (suspected) exposure to unspecified communicable disease
	Z22.51	Carrier of Viral Hepatitis B
	Z72.5	High Risk Sexual behavior
	Z72.51	High risk heterosexual behavior
	Z72.52	High risk homosexcual behavior
	Z72.53	High risk bisexual behavior
	Z77.21	Contact with and (suspected) exposure to potentially hazardous body fluids
	Z77.9	Other contact with and (suspected) exposure hazardous to health
Agalsidase beta - Fabrizyme®	E75.21	Fabry (-Anderson) Disease
Alglucoside alfa - Lumizyme®	E74.02	Pompe Disease
Amikacin Inhalation Suspension - Arikayce®	A31.0, A31.2	Mycobacterium avium complex
Eculizumab - Soliris®	D59.3	Hemolytic-Uremic Syndrome
	D59.5	Paroxysmal Nocturnal Hemoglobinuria (Marchiafava-Micheli)
	G70.0*	Myasthenia Gravis
	G36.0	Neuromyelitis Optica Spectrum Disorder (NMOSD)

~~FAX this form to:~~
~~(318) 812-2940~~

~~Or mail to:~~
~~La. Medicaid Rx PA Operations~~
~~ULM College of Pharmacy~~
~~1800 Bienville Drive, Rm 270~~
~~Monroe, LA 71201-3765~~

~~State of~~ LOUISIANA MEDICAID
~~Department of Health~~
~~Bureau of Health Services Financing~~
~~Louisiana Medicaid Prescription Prior Authorization Program~~

REQUEST FOR RECONSIDERATION

Form: Rx PA02
Issue Date: 10/15/12
Revised Date: ~~6/6/19~~8/21/19

~~Voice Phone:~~
~~(866) 730-4357~~

Date of Request: _____

Original PA #: _____

The prescriber may request reconsideration of a drug prior authorization denial by completing the information on the form and faxing to the ~~number above~~appropriate plan. As necessary, please provide copies of the recipient's medical records and/or lab results in addition to any supportive peer-reviewed literature to assist in evaluating therapy.

I. Provider Information		**II. Recipient Information**
Provider Name (print):		Recipient Name (print):
Provider Specialty:	Medicaid Provider ID:	Recipient Medicaid ID:
Provider Phone:	Provider Fax:	Recipient Date of Birth:
Office Contact Name:	EPSDT Support Coordinator (Name/Address): *(optional)*	Medication Allergies:

III. Drug Information (One drug request per form.)

Drug Name and Strength: ~~Dosage Form:~~	Dosage Form:~~Dosage Interval (sig):~~	Quantity Prescribed:
Dosage Interval (sig):~~Diagnosis relevant to **this** request:~~		
☐ Diagnosis relevant to **this** request:~~Expected length of therapy:~~		

A. Is recipient currently treated on this medication?
Yes. If yes, how long?_____{If yes, go to Item B} ☐ No {Skip Items B & C. Go directly to Item D}

B. Is this request for continuation of a previous approval?
Yes {If yes, go to Item C} No {Skip Item C. Go directly to Item D}

C. Has strength, dosage, or quantity required per day increased or decreased?
Yes ~~{If yes, go to Item D}~~ ☐ No ~~{Skip Item D. Indicate rationale for continuation in Section IV and submit form.}~~

D. Please indicate previous treatment (including treatment with the requested medication) and outcomes below:

Drug Name (include strength and dosage)	**Dates of Therapy**	**Reason for Discontinuation**
1.		
2.		
3.		
4.		

NOTE: Confirmation of use will be made from recipient history on file; prior use of preferred drugs is a part of the exception criteria.

IV. Rationale for Request / Pertinent Clinical Information (Required for all Prior Authorizations)

Appropriate clinical information to support the request on the basis of medical necessity must be submitted.	**Provider Signature:**	**Date:**

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INCOMPLETE FORMS WILL DELAY PROCESSING

A final determination (approval or denial) ~~through ULM Prior Authorization Unit~~ will be made within 3 business days from the date of receipt of this request. This decision will be based on the clinical aspects of the case.

☐ **Check here to request telephone consultation**

Louisiana Fee-For-Service Medicaid
Palivizumab (Synagis®) for ~~the 2018-2019~~ Respiratory Syncytial Virus (RSV) Season

Palivizumab is indicated for the prevention of serious lower respiratory tract infection caused by respiratory syncytial virus (RSV) in selected infants and young children at high risk of RSV disease. Monthly prophylaxis should be discontinued in any infant receiving monthly palivizumab prophylaxis who experiences a breakthrough RSV hospitalization.

Clinical ~~Pre-~~Authorization Criteria

All prescriptions for palivizumab for recipients in Fee-For-Service Medicaid require clinical ~~pre-~~authorization. **Prescribing providers,** not the pharmacy, manufacturer or any other third party entity, must complete the *Palivizumab Clinical ~~Pre-~~Authorization Form* and fax it **directly** to ~~LA Medicaid Rx PA Operations at the University of Louisiana at Monroe College of Pharmacy at **866-797-2329**~~the recipient's plan at the fax number found on the attached fax cover sheet. Any requests submitted early will not be processed prior to the start of RSV season. Prescribing providers will be notified by fax or mail of the outcomes of clinical ~~pre-~~authorization requests.

Clinical ~~pre-~~authorization will be considered for approval when requests meet the following criteria:

- Palivizumab clinical ~~pre-~~authorization requests will be considered in accordance with an RSV season of November 1~~, 2018~~ through March 31~~, 2019~~; **AND**

- Recipient must meet gestational age **AND** chronological age requirements for the ICD-10-CM diagnosis code(s) and/or other qualifying risk factor(s) submitted with the request. Supporting documentation (i.e. progress notes, hospital discharge notes, pediatric cardiologist consult notes, chart notes, pharmacy profiles, etc.) is required and must be submitted with each request. Requests for palivizumab will be considered for approval when **ONE** of the following 'high-risk' criteria are met:

1. **Infant born prematurely without chronic lung disease (CLD) OR without hemodynamically significant cyanotic or acyanotic heart disease or without other listed 'high-risk' factors:**
   - The infant is younger than 12 months of age on November 1, ~~2018,~~ **AND** was born before 29 weeks, 0 days' (≤ 28 weeks, 6 days') gestation.

2. **Infant with chronic lung disease (CLD)** (one of the criteria sets below must be met):
   - **SET 1:** Infant diagnosed with CLD who is 12 months of age or younger, whose first birthday is on or after November 1, ~~2018,~~ AND the infant was born at < 32 weeks, 0 days' gestation **AND** the infant required > 21% oxygen for at least 28 days after birth; **OR**
   - **SET 2:** Infant diagnosed with CLD who is 24 months of age or younger, whose second birthday is on or after November 1, ~~2018,~~ infant's second dosing season, **AND** the infant was born at < 32 weeks, 0 days' gestation **AND** the infant required > 21% oxygen for at least 28 days after birth **AND** the infant has required medical therapy (i.e., chronic systemic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the six (6) months before November 1, ~~2018,~~ the start of the infant's second (RSV) season.

3. **Infant with congenital heart disease (CHD):**
   - The infant's first birthday is on or after November 1~~, 2018~~; **AND**

- The infant meets one of the following hemodynamically significant conditions:
  - The infant has cyanotic heart defect(s) and decision for use of palivizumab was made with pediatric cardiologist consultation; **OR**
  - The infant has acyanotic heart disease **AND** is receiving medication to control congestive heart failure **AND** will require a cardiac surgical procedure; **OR**
  - The infant has moderate to severe pulmonary hypertension; **OR**
  - The infant has lesions that have been adequately corrected by surgery but continues to require medication for congestive heart failure.

4. **Infant with cardiac transplant**
   - The infant is younger than 2 years of age on November 1~~, 2018~~; **AND**
   - The infant has undergone or will undergo cardiac transplantation from November 1~~, 2018~~ through March 31~~, 2019~~.

5. **Infant with a congenital anatomic pulmonary abnormality or neuromuscular disease:**
   - The infant's first birthday is on or after November 1~~, 2018~~; **AND**
   - The infant's congenital anatomic pulmonary abnormality or neuromuscular disease impairs the ability to clear secretions from the upper airways because of ineffective cough.

6. **Immunocompromised infant:**
   - The infant's second birthday is after November 1~~, 2018~~; **AND**
   - The child is/will be profoundly immunocompromised (for example, receiving chemotherapy or immunosuppressive therapy) from November 1~~, 2018~~ through March 31~~, 2019~~.

Medical Reconsideration

Medical Reconsideration of a denied clinical ~~pre-~~authorization decision may be requested by the prescribing provider. Reconsideration requires completion of the ~~Palivizumab~~ Request for Reconsideration form ~~available at www.lamedicaid.com~~linked on the PDL. The form must be completed in full and signed by the prescribing provider. Signature stamps and proxy signatures are not acceptable and will be returned to the requesting provider. The completed form must be faxed from the prescribing provider to the ~~LA Medicaid Rx PA Operations at the University of Louisiana at Monroe College of Pharmacy at 318-812-2940~~recipient's plan at the fax number found on the attached fax cover sheet.

Point-of-Sale (POS) Requirements

Age Restriction

- Palivizumab claims for recipients who are twenty-four (24) months of age or younger as of November 1~~, 2018~~ meet the POS age requirement.

Maximum Number of Doses

- Up to a maximum number of five (5) doses will be reimbursed during the RSV season. Qualifying infants born during the RSV season require fewer doses. For example, infants born in January would receive their last dose in March. A claim submitted for palivizumab outside the maximum number of doses allowed will deny with:

  NCPDP rejection code 88 (DUR Reject Error) mapped to
  EOB code 656 (Exceeds Maximum Duration of Therapy)

Early Refill

- Palivizumab claims will only process for payment every twenty-eight (28) days.

PALIVIZUMAB CRITERIA ICD-10-CM CODE and MEDICATION LIST

*Note: **ANY** accepted diagnosis/ICD-10-CM Code listed on the clinical ~~pre~~ authorization form **MUST** have supporting documentation attached. Supporting documentation is supplemental information submitted to support the patient meeting the criteria and may include copies of progress notes, hospital discharge notes, pediatric cardiologist consult notes, chart notes, pharmacy profiles, etc.*

I. Neuromuscular Disorders

Acceptable ICD-10 codes include:

A80.0-A80.39	Infantile paralysis
G31.9	Cerebral degenerations
G25.3	Myoclonus
G11.1, G11.4	Spinocerebellar disease
G12.0	Werdnig-Hoffman disease (Infantile spinal muscular atrophy)
G12.1, G12.8, G12.9	Spinal muscular atrophy
G12.2*	Motor neuron disease

Exclude (but not limited to) the following (i.e. the following are **NOT** accepted):

G80*	Cerebral palsy
G40.3*	Generalized convulsive epilepsy
G40.4*	Grand mal seizures
G40*	Epilepsy
Q05*	Spina bifida
P90	Newborn seizures
R56*	Infantile seizures

II. Congenital Abnormalities of the Airways

Acceptable ICD-10 codes include:

G47.35	Congenital central alveolar hypoventilation syndrome
Q32.0, Q32.1	Other diseases of the trachea and bronchus, not elsewhere classified (Must specify Tracheomalacia or tracheal stenosis)
Q31.1, Q31.5, Q32.1, Q32.4	Other anomalies of larynx, trachea, and bronchus (Must specify congenital tracheal stenosis, subglottic stenosis, atresia of trachea, laryngomalacia, or absence or agenesis of bronchus, trachea)
Q33.0	Congenital cystic lung
Q33.3, Q33.6	Agenesis, hypoplasia, and dysplasia of the lung
Q33.4	Congenital bronchiectasis
Q38.2	Macroglossia
Q38.5	Uvula anomaly
J98.6	Diaphragmatic paralysis
Q87.3	Beckwith-Wiedemann syndrome

Exclude (but not limited to) the following (i.e. the following are **NOT** accepted):

Q33.9	Anomaly of lung, unspecified
Q33.1, Q33.8	Other anomaly of the lung

III. Chronic Lung Disease

Acceptable ICD-10 code:

P27*	Chronic respiratory disease arising in the perinatal period (CLD/BPD/Interstitial pulmonary fibrosis of prematurity/Wilson-Mikity syndrome)

Exclude (but not limited to) the following (i.e. the following are **NOT** accepted):

J05.0	Croup
J06*	URI
J20*	Bronchitis
J21*	Bronchiolitis
J45*	Asthma
R06.2	Wheezing

IV. Congenital Heart Diseases (CHD) Per AAP guidelines, prophylaxis with palivizumab in children with CHD should be made on the degree of cardiovascular compromise. CHD that is deemed hemodynamically insignificant will not meet criteria. Documentation must specifically support CHD being hemodynamically significant (e.g. medications, etc.).

Acceptable ICD-10 codes include:

A. Acyanotic CHD: Must currently be receiving medication to control CHF (see below)

Q23.0	Aortic stenosis
I37.0, I37.1, I37.2, Q22.1, Q22.2	Pulmonary valve disorders (incompetence, insufficiency, regurgitation, and stenosis)
I42*, I43	Cardiomyopathy (must be moderate to severe)
Q21.0	Ventricular septal defect
Q21.1	Atrial septal defect
Q21.2	Atrioventricular canal (endocardial cushion defect)
Q22.3	Anomalies of pulmonary valve congenital
Q22.1	Pulmonic stenosis
Q23.0	Congenital stenosis of aortic valve (congenital aortic stenosis) [Excludes: congenital subaortic stenosis; supravalvular aortic stenosis]
Q23.3	Congenital mitral insufficiency
Q25.0	Patent ductus arteriosus
Q25.1	Coarctation of the aorta
Q25.2, Q25.3	Atresia and stenosis of aorta (absence, aplasia, hypoplasia, stricture of the aorta) Supra (valvular)-aortic stenosis [Excludes: congenital aortic (valvular) stenosis or stricture; hypoplasia of aorta in hypoplastic left heart syndrome]

B. Cyanotic CHD: Does not require use of medication/must not have had or completed surgical correction

Q20.0	Truncus arteriosus
Q20.3	Transposition of the great vessels
Q21.3	Tetralogy of Fallot
Q22.0	Atresia, congenital
Q22.4	Tricuspid atresia and stenosis, congenital
Q22.5	Ebstein's anomaly
Q23.4	Hypoplastic left heart
Q22.6	Hypoplastic right heart
Q25.5	Pulmonary atresia
Q26.2	Total anomalous pulmonary venous return

C. Pulmonary Hypertension:

I26.0*	Acute cor pulmonale
I27.0	Primary pulmonary hypertension
I27.2	Other chronic pulmonary heart disease (pulmonary hypertension, secondary)
P29.3	Persistent fetal circulation (persistent pulmonary hypertension/primary pulmonary hypertension of newborn)

***any number or letter or combination of **UP TO FOUR** numbers and letters of an assigned ICD-10-CM diagnosis code

ACCEPTABLE MEDICATIONS USED IN CHD

Digoxin
Beta Blockers
Calcium Channel Blockers
ACE Inhibitors
Nitroglycerin
Anti-Coagulants
Supplemental oxygen
Diuretics

Reference

STAT!Ref - Red Book®: 2018-2021 Report of the Committee on Infectious Diseases. Online.statref.com. http://online.statref.com/publictitleinfo/titleinfo.aspx?fxid=76 Published 2018.

~~Fax this completed form to:~~
~~La Medicaid Rx PA Operations~~
~~ULM College of Pharmacy~~
~~1800 Bienville Drive~~
~~Monroe, LA 71201-3765~~
~~FAX 866-797-2329~~

~~State of~~ Louisiana Medicaid
~~Department of Health~~
~~Bureau of Health Services Financing~~

Palivizumab Clinical ~~Pre-~~Authorization Form
For ~~2018-2019~~ RSV Season

Palivizumab Form: Rx PA01P
Revised: 8/19/2019~~05/15/2018~~

~~VOICE PHONE 866-730-4357~~

Request must be faxed. Please type or print legibly. Incomplete forms will not be approved. Date of Request _____

Prescribing Provider Information	**Recipient Information**	
Name (Last, First)	Name (Last, First)	
LA Medicaid Prescribing Provider Number / NPI	LA Medicaid CCN or Recipient Number	
Call-Back Phone Number (include area code)	Date of Birth (mm/dd/yy)	Gestational Age (weeks/days)
FAX Number (include area code)	Recipient Current Weight _____kg as of _____ (mm/dd/yy)	
Drug and Strength Requested	Diagnosis Code(s) (ICD-10-CM) to Justify Palivizumab Use	
Office Contact Name	EPSDT Support Coordinator (Name / Address) (optional)	

Does the patient have additional insurance coverage (TPL)? ___ Yes ___ No If Yes, please contact TPL to determine coverage for this drug.

Check the applicable age/condition. For chronic lung disease (CLD) of prematurity/congenital heart disease (CHD), attach supporting documentation (e.g. hospital birth discharge notes, pediatric cardiologist consult notes and/or chart notes) for any submitted qualifying criteria or ICD-10 diagnosis code(s). Please refer to the Palivizumab Criteria ICD-10-CM Diagnosis Code and Medication List.

- ☐ Infant's gestational age is less than 29 weeks, 0 days AND infant's chronological age is less than 12 months old as of November 1~~, 2018~~.
- ☐ Infant is 12 months old or younger (infant's first birthday is on or after November 1~~, 2018~~) with CLD of prematurity, defined as an infant with gestational age of less than 32 weeks, 0 days who required supplemental oxygen greater than 21% for at least the first 28 days after birth.
- ☐ Infant is 24 months old or younger (infant's second birthday is on or after November 1~~, 2018~~) with CLD of prematurity, defined as an infant with gestational age of less than 32 weeks, 0 days who required supplemental oxygen greater than 21% for at least the first 28 days after birth AND infant continued to require medical support (chronic systemic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the infant's second respiratory syncytial virus (RSV) season, which is November 1~~, 2018~~.
- ☐ Infant is 12 months old or younger (infant's first birthday is on or after November 1~~, 2018~~) with hemodynamically significant CHD WITH: (check one) (list applicable diagnosis codes _____)
  - _____ acyanotic heart disease AND is receiving medication to control congestive heart failure (CHF) such as diuretics, ACE inhibitors, beta-blockers or digoxin AND will require a cardiac surgical procedure.
  - _____ moderate to severe pulmonary hypertension.
  - _____ lesions that have been adequately corrected by surgery but continues to require medication for CHF such as diuretics, ACE inhibitors, beta-blockers or digoxin.
  - _____ cyanotic heart defect(s) AND decision for use of palivizumab was made with pediatric cardiologist consultation.
- ☐ Infant is younger than 2 years old on November 1~~, 2018~~ AND infant has undergone (or will undergo) cardiac transplantation during the RSV season (November 1~~, 2018~~ through March 31~~, 2019~~).
- ☐ Infant is 12 months old or younger (infant's first birthday is on or after November 1~~, 2018~~) AND infant has a congenital anatomic pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airway because of ineffective cough.
- ☐ Infant is younger than 24 months old on November 1~~, 2018~~ AND infant will be profoundly immunocompromised during RSV season (November 1~~, 2018~~ through March 31~~, 2019~~) due to _____.

Is the patient currently in the hospital? _____Yes _____No

Has the patient been in the hospital since the start of the current RSV season (November 1~~, 2018~~)? _____Yes _____No

If Yes, was a dose of palivizumab administered while patient was hospitalized? ____Yes ____No If Yes, please provide date _____.

Prescribing Physician Signature:* _____ Date:_____

**(Signature stamps and proxy signatures are not acceptable)*

Louisiana Medicaid
Pegvaliase-pqpz (Palynziq™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for pegvaliase-pqpz (Palynziq™).

*Pegvaliase-pqpz (Palynziq™) has a **Black Box Warning** and is available only through a restricted program under a **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to prescribing information for details.*

Pharmacy reimbursement of pegvaliase-pqpz (Palynziq™) requires a pharmacy claim for an auto-injectable epinephrine product within the previous year. If the auto-injectable epinephrine product is prescribed at the same time as pegvaliase-pqpz (Palynziq), the auto-injectable epinephrine claim must be submitted first.

Approval criteria for requests to initiate treatment with pegvaliase-pqpz (Palynziq™)

- The recipient is at least 18 years of age on the date of the request; **AND**
- The recipient has a diagnosis of phenylketonuria (PKU); **AND**
- The following is true and is **stated on the request:**
    - The recipient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management. [Existing management includes, but is not limited to dietary phenylalanine and/or protein restriction, and use of Kuvan (sapropterin dihydrochloride)]; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - Pegvaliase-pqpz (Palynziq™) is prescribed by, or in consultation with, a healthcare provider experienced in the management of PKU; **AND**
    - The dose does not exceed the recommended dosing from the prescribing information; **AND**
    - Pegvaliase-pqpz (Palynziq™) and sapropterin dihydrochloride (Kuvan®) will not be used concomitantly; **AND**
    - The prescriber has prescribed an auto-injectable epinephrine prior to the first dose of pegvaliase-pqpz (Palynziq™), and the recipient (and observer if applicable) have been instructed on how to recognize and manage the signs and symptoms of anaphylaxis; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of pegvaliase-pqpz.

Reauthorization or Continuation Criteria:

- The recipient continues to meet initial approval criteria; **AND**
- The recipient has had a positive clinical response, shown by **ONE** of the following that is **stated on the request**:
    - The recipient has achieved at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline; **OR**
    - The recipient's blood phenylalanine concentration is less than or equal to 600 micromol/L.

Duration of initial and reauthorization approval: 12 months

Reference

Palynziq (pegvaliase-pqpz) [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; Retrieved from https://www.palynziq.com/prescribinginformation.pdf

Louisiana Medicaid
Collagenase (Santyl®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request prior authorization to override the quantity limit for collagenase (Santyl®).

Collagenase (Santyl®) is subject to a quantity limit of seven (7) 90-gram tubes per prescription fill, for a total of 630 grams. Any prescription claim for greater than 630 grams of collagenase (Santyl®) will require prior authorization.

Override approval criteria

- **ONE** of the following is true and is **stated on the request**:
    - The recipient's wound shows some evidence of progress toward healing; **OR**
    - The recipient's wound shows no evidence of progress toward healing, and re-evaluation of the treatment plan includes the determination to:
        i. Modify the current interventions, and these modified interventions include use of collagenase (Santyl®); **OR**
        ii. Continue the current interventions, and the clinician documents the rationale for continuing the present treatment to explain why some, or all, of the plan's interventions remain relevant despite little or no apparent healing; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no inappropriate concomitant drug therapies or disease states.

Duration of override approval : 1 month

References

Santyl (collagenase) [package insert]. Fort Worth, TX: Smith & Nephew, Inc.; 2016. https://www.santyl.com/pdf/SANTYL-PI.pdf

State Operations Manual Appendix PP-Guidance to Surveyors for Long Term Care Facilities. Revised 11/22/17. pp. 248-266, 272, 273. *Cms.Gov*, 2019, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

Revision	Date
New Criteria Document	November 2019

Louisiana Medicaid
Risankizumab-rzaa (Skyrizi™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for risankizumab-rzaa (Skyrizi™).

Approval criteria for requests to initiate treatment

- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of moderate-to-severe plaque psoriasis; **AND**
- The following is true and is **stated on the request**:
    - The prescriber is (or has consulted with) a rheumatologist or dermatologist; **AND**
    - The recipient has a contraindication to, documented intolerance or treatment failure with an adequate trial (6-12 weeks) of **AT LEAST ONE** of the following therapies: phototherapy, methotrexate, and/or cyclosporine; **AND**
    - The recipient has Body Surface Area (BSA) involvement of at least 3% or involvement of the palms, soles, head and neck or genitalia, causing disruption in normal activities and/or employment; **AND**
    - The dose does not exceed 150mg at Week 0, Week 4 and every 12 weeks thereafter**; AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The recipient will not receive the requested medication in combination with any other cytokine or CAM antagonist; **AND**
    - The recipient has no evidence of an active infection (including Hepatitis B virus and/or tuberculosis) within the last 180 days; **AND**
    - The recipient was tested for latent tuberculosis in the past 30 days, and test results are documented in the medical record. If the recipient tested positive for latent TB, treatment for TB will begin prior to starting the requested medication; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling**.**

Reauthorization Criteria

- Recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that there is evidence of a positive response to treatment as indicated by improvement in signs and symptoms compared to baseline, or by halting of disease progression (no progression of disease signs and symptoms as compared to baseline).

Initial Approval: 6 months
Reauthorization Approval: 12 months

References

Gottlieb, A, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol. 2008 May;58(5):851-64. https://www.aad.org/practicecenter/quality/clinical-guidelines/psoriasis

Skyrizi® (risankizumab-rzaa) [package insert]. North Chicago, IL: AbbVie Inc.; 2019. https://www.rxabbvie.com/pdf/skyrizi_pi.pdf

Revision	Date
New Criteria Document	November 2019

Louisiana Medicaid
Antipsychotic Therapeutic Duplication

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request authorization to override the therapeutic duplication edit for antipsychotics.

ALL of the following criteria must be met:

- **ONE** of the following must be true and **is stated on the request**:
    - The recipient had a cross-titration and/or taper of antipsychotic therapy (include both agents' dosage and dates of therapy); **OR**
    - The recipient had an inadequate response or adverse reaction to **TWO** antipsychotic monotherapy trials (include trial duration with dates of use documented on request); **OR**
    - The recipient had a recent psychiatric hospitalization and was discharged on the current antipsychotic regimen (include date of discharge); **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The recipient has a treatment-resistant psychiatric condition; **AND**
    - Prescriber is a psychiatrist or a psychiatrist has been consulted; **AND**
    - The prescribing information for the requested medication(s) has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information(s) have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that would limit the use of the requested medication(s) and will not be receiving the requested medication(s) in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria:

- Recipient continues to meet initial approval criteria; **AND**
- Prescriber states on the request that there is evidence of a positive response to therapy as indicated by improvement in signs and/or symptoms compared to baseline.

Duration of authorization approval, both initial and reauthorization: 12 months

Louisiana Medicaid
Patiromer (Veltassa®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for patiromer (Veltassa®).

Approval criteria for requests to initiate treatment

- The recipient is at least 18 years of age on the date of the request; **AND**
- The recipient has a diagnosis of non-life-threatening hyperkalemia; **AND**
- The dose does not exceed 25.2 grams once a day; **AND**
- The quantity does not exceed 1 packet per day; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - Patiromer will **NOT** be used as an emergency treatment for life threatening hyperkalemia because of its delayed onset of action; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of patiromer.

Reauthorization or Continuation Criteria:

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber states on the request that the recipient is established on patiromer therapy and that there has been a positive clinical response.

Duration of authorization approval, both initial and reauthorization: 12 months

Note: Patiromer (Veltassa®) has a quantity limit at Point-of-Sale: Limited to 30 packets per 30 days.

Reference

Veltassa (patiromer) [package insert]. Redwood City, CA: Relypsa, Inc,; 2018. Retrieved from https://www.veltassa.com/pi.pdf

Louisiana Medicaid
Onasemnogene abeparvovec-xioi (Zolgensma®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for onasemnogene abeparvovec-xioi (Zolgensma®).

*Onasemnogene abeparvovec-xioi (Zolgensma®) has a **Black Box Warning**. Please refer to prescribing information for details.*

Approval criteria for onasemnogene abeparvovec-xioi (Zolgensma®) requests

- The recipient has reached full-term gestational age (defined as 39 weeks 0 days) on the date of the request (documentation showing gestational age at birth [in weeks and days] must be provided with the request); **AND**
- The recipient is less than 2 years of age on the date of the request; **AND**
- Onasemnogene abeparvovec-xioi (Zolgensma®) is prescribed by, or the request states that onasemnogene abeparvovec-xioi (Zolgensma®) is being prescribed in consultation with, a neurologist experienced in the treatment of SMA; **AND**
- The following are true and **stated on the request:**
    - The recipient has a diagnosis of spinal muscular atrophy (SMA) with bi-allelic mutations in the *survival motor neuron 1 (SMN1)* gene; **AND**
    - The recipient **DOES NOT HAVE advanced SMA** (e.g., complete paralysis of limbs, permanent ventilator dependence); **AND**
    - The recipient **has never received a dose** of onasemnogene abeparvovec-xioi (Zolgensma®); **AND**
    - The recipient has a baseline anti-AAV9 antibody titer $\leq$ 1:50, measured using an enzyme-linked immunosorbent assay (ELISA) **[date and results must be written on the request]**; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, prior treatment requirements (such as systemic corticosteroids) and required storage and handling procedures; **AND**
    - Where feasible, the recipient's vaccination schedule has been adjusted to accommodate concomitant corticosteroid administration prior to and following onasemnogene abeparvovec-xioi (Zolgensma®) infusion (seasonal RSV prophylaxis is not precluded); **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of onasemnogene abeparvovec-xioi (Zolgensma®).

Duration of Approval: 1 month

Reference

Zolgensma (onasemnogene abeparvovec-xioi) [package insert]. Bannockburn, IL: AveXis, Inc.; 2019. Retrieved from https://www.avexis.com/content/pdf/prescribing_information.pdf