Louisiana Medicaid | Provider UPDATE

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Food and Drug Administration (FDA) Drug Safety Communication Regarding Serious Breathing Problems with Gabapentin and Pregabalin

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Table of Contents

On December 19, 2019, the U.S. Food and Drug Administration (FDA) released an FDA Drug Safety Communication warning that serious breathing difficulties may occur in patients using gabapentin or pregabalin who have respiratory risk factors. These include the use of opioid pain medicines and other drugs that depress the central nervous system (CNS) and conditions such as chronic obstructive pulmonary disease (COPD) that reduce lung function. The elderly are also at higher risk. The FDA's evaluation indicated that the use of these medicines, which are often referred to as gabapentinoids, has been growing for prescribed medical use, as well as misuse and abuse. Gabapentinoids are often being combined with CNS depressants, which increases the risk of respiratory depression. The FDA is requiring new warnings about the risk of respiratory depression to be added to the prescribing information of the gabapentinoids. In addition, the FDA has also required the drug manufacturers to conduct clinical trials to further evaluate their abuse potential, particularly in combination with opioids, because misuse and abuse of these products together is increasing, and co-use may increase the risk of respiratory depression. Special attention will be paid to the respiratory depressant effects during this abuse potential evaluation.

The FDA stated that serious, life-threatening, and fatal respiratory depression has been reported with the gabapentinoids. Most cases occurred in association with coadministered CNS depressants, especially opioids, in the setting of underlying respiratory impairment, or in the elderly. The FDA evaluation of respiratory depression with the gabapentinoids provides some evidence contrary to the widely held belief that gabapentinoids lack drug interactions and have wide therapeutic indices. Published studies demonstrate these drugs can behave in an additive way to potentiate CNS and respiratory depression. The management of respiratory depression may include close observation, supportive measures, and reduction or withdrawal of CNS depressants, including the gabapentinoid.
Healthcare professionals should start gabapentinoids at the lowest dose and monitor patients for symptoms of respiratory depression and sedation when co-prescribing gabapentinoids with an opioid or other CNS depressant such as a benzodiazepine. Patients with underlying respiratory disease and elderly patients are also at increased risk and should be managed similarly.

The FDA will continue to monitor these medicines as part of their routine monitoring of all FDA-approved drugs. To help FDA track safety issues with medicines, report side effects from gabapentin, pregabalin, or other medicines to the FDA MedWatch program, available at www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.

Review of Gabapentin and Pregabalin Products

Brand (Generic)	How Supplied	Indications	Dosage and Administration
Gralise® (gabapentin)	Tablets: 300mg 600mg	• Postherpetic neuralgia (PHN)	Titrate to an 1800mg dose taken orally once daily with the evening meal. Refer to the prescribing information for the recommended titration schedule.
Horizant® (gabapentin enacarbil extended-release)	Extended-release tablets: 300mg 600mg	• Postherpetic neuralgia (PHN) • Moderate-to-severe primary Restless Legs Syndrome (RLS)	PHN: Initial dose of 600mg in the morning for 3 days, then increase to 600mg twice daily beginning on day 4. A daily dose greater than 1200mg provided no additional benefit. RLS: 600mg once daily taken at about 5pm. A dose of 1200mg once daily provided no additional benefit compared to the 600mg dose but caused an increase in adverse reactions.
Lyrica® (pregabalin)	Capsules: 25mg 50mg 75mg 100mg 150mg 200mg 225mg 300mg Oral Solution: 20mg/mL	• Neuropathic pain associated with diabetic peripheral neuropathy (DPN) • Postherpetic neuralgia (PHN) • Fibromyalgia • Neuropathic pain associated with spinal cord injury • Adjunctive therapy for the treatment of partial-onset seizures in patients 1 month of age and older	Adult Indications: Initial dose of 150mg/day 2-3 divided doses per day Pediatric patients with partial-onset seizures: Initial dose of 2.5mg/kg/day for those weighing 30 kg or more AND 3.5mg/kg/day for those weighing less than 30 kg. For maximum doses, refer to current prescribing information.
Lyrica® CR (pregabalin extended-release)	Extended-release tablets: 82.5mg 165mg 330mg	• Neuropathic pain associated with diabetic peripheral neuropathy (DPN) • Postherpetic neuralgia (PHN)	Initial dose of 165mg/day Given once daily Maximum dose for DPN pain: 330mg/day within 1 week of initial dose Maximum dose for PHN: 330mg/day within 1 week of initial dose, with a maximum dose of 660mg/day
Neurontin® (gabapentin)	Capsules: 100mg 300mg 400mg Tablets: 600mg 800mg Oral Solution: 250mg/5mL	• Postherpetic neuralgia (PHN) • Adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years and older with epilepsy	PHN: Day 1 – Single 300mg dose Day 2 – 600mg/day in divided doses Day 3 – 900mg/day in divided doses Then titrated upward as needed to 1800mg/day. Epilepsy with Partial Onset Seizures in patients 12 years of age and above: Initial dose - 300mg three times daily. May be titrated up to 600mg three times a day. Dosages up to 2400mg/day have been well tolerated. Epilepsy with Partial Onset Seizures in patients 3 to 11 years of age: Refer to prescribing information.

Adverse Reactions, Precautions, and Warnings

Gralise®

- Gralise® is not interchangeable with other gabapentin products because of differing pharmacokinetic profiles that affect the frequency of administration.
- The most common adverse reaction is dizziness.
- The safety and effectiveness in the management of postherpetic neuralgia in patients less than 18 years of age have not been studied.
- Gralise® tablets should swallowed whole. Do not crush, split, or chew the tablets.
- If the dose of Gralise® is reduced, discontinued, or substituted with an alternative medication, this should be done gradually over a minimum of 1 week or longer at the discretion of the prescriber.

Horizant®

- Horizant® is not interchangeable with other gabapentin products.
- The most common adverse reactions include somnolence/sedation and dizziness.
- The safety and effectiveness have not been studied in pediatric patients.
- Horizant® tablets should be swallowed whole. Do not cut, crush or chew the tablets.

Lyrica® and Lyrica® CR

- Hypersensitivity reactions (e.g., hives, dyspnea, and wheezing) can occur with pregabalin. Discontinue immediately in these patients.
- Pregabalin may cause peripheral edema. Exercise caution when coadministering pregabalin and thiazolidinedione antidiabetic agents.
- The safety and effectiveness of Lyrica® CR in pediatric patients have not been established.
- Increased seizure frequency or other adverse reactions may occur if rapidly discontinued. Withdraw gradually over a minimum of 1 week.
- Some of the most common adverse reactions in adults are dizziness, somnolence, dry mouth, blurred vision, and weight gain.
- The most common adverse reactions in pediatric patients for the treatment of partial-onset seizures are increased weight and increased appetite.

Neurontin®

- Some of the most common adverse reactions in patients greater than 12 years of age include dizziness, somnolence, peripheral edema, ataxia, fatigue, and nystagmus.
- When Neurontin® is used for epilepsy in pediatric patients between the ages of 3 and 12, the most common adverse reactions include viral infection, fever, nausea / vomiting, and somnolence. Gabapentin use in these patients is also associated with the occurrence of CNS related adverse reactions, such as emotional lability, hostility, thought disorders, and hyperkinesia. Monitor these patients for neuropsychiatric adverse reactions.
- Neurontin® can cause anaphylaxis and angioedema after the first dose or at any time during treatment. Signs and symptoms in reported cases have included difficulty breathing, swelling of the lips, throat, and tongue, and hypotension requiring emergency treatment.
- Increased seizure frequency may occur in patients with seizure disorders if Neurontin® is abruptly discontinued.

Gabapentinoids (all gabapentin and pregabalin products)

- May cause dizziness and somnolence and impair ability to drive or operate machinery.
- The risk of suicidal thoughts or behavior may be increased with gabapentinoids.
- Gabapentinoids require dosage adjustments in patients with reduced renal function.
- Gabapentinoids used for analgesia or seizure control should be tapered prior to discontinuation. See the prescribing information for specific tapering guidance.
- Monitor for symptoms of respiratory depression and sedation, especially when coprescribing gabapentinoids with an opioid or other CNS depressant such as a benzodiazepine or when prescribing to patients with underlying respiratory impairment, or elderly patients.

References
Gralise [package insert]. Newark, CA: Depomed Inc; September 2015. https://www.gralise.com/pdf/Gralise_Prescribing_Information.pdf

Horizant [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2016. https://www.horizant.com/pdf/Horizant-Prescribing-Information.pdf

Lyrica [package insert]. New York, NY: Pfizer Inc; June 2019. http://labeling.pfizer.com/showlabeling.aspx?id=561

Lyrica CR [package insert]. New York, NY: Pfizer Inc; June 2019. http://labeling.pfizer.com/ShowLabeling.aspx?id=9678

Neurontin [package insert]. New York, NY: Pfizer Inc; August 2019. http://labeling.pfizer.com/ShowLabeling.aspx?id=630

U.S. Food and Drug Administration. FDA Drug Safety Communication. FDA warns about serious breathing problems with seizure and nerve pain medicines gabapentin (Neurontin, Gralise, Horizant) and pregabalin (Lyrica, Lyrica CR). December 2019. https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-serious-breathing-problems-seizure-and-nerve-pain-medicines-gabapentin-neurontin

PHARMACY FACTS

Program Updates from Louisiana Medicaid

Pharmacy Facts can also be found online at: http://ldh.la.gov/index.cfm/page/3036.

January 3, 2020

It has just come to our attention that correspondence went to pharmacy providers regarding Point of Sale Certification. This recertification information is used internally by pharmacy staff to ensure we have appropriate contact information as well as personnel for each enrolled pharmacy provider.

We apologize that the packet was released later than our usual date in October of each year. Providers have until (or before) March 31, 2020 to complete the form.

Brand Over Generic List

The Louisiana Department of Health (LDH) scheduled a Pharmaceutical & Therapeutics (P&T) meeting in November 2019. Although there was a quorum, it was not the appropriate mix of professionals required in the bylaws. Therefore, the Brand Over Generic list from the April 2019 P&T meeting will remain in place until the next meeting in the spring of 2020. For your reference, the list is below:

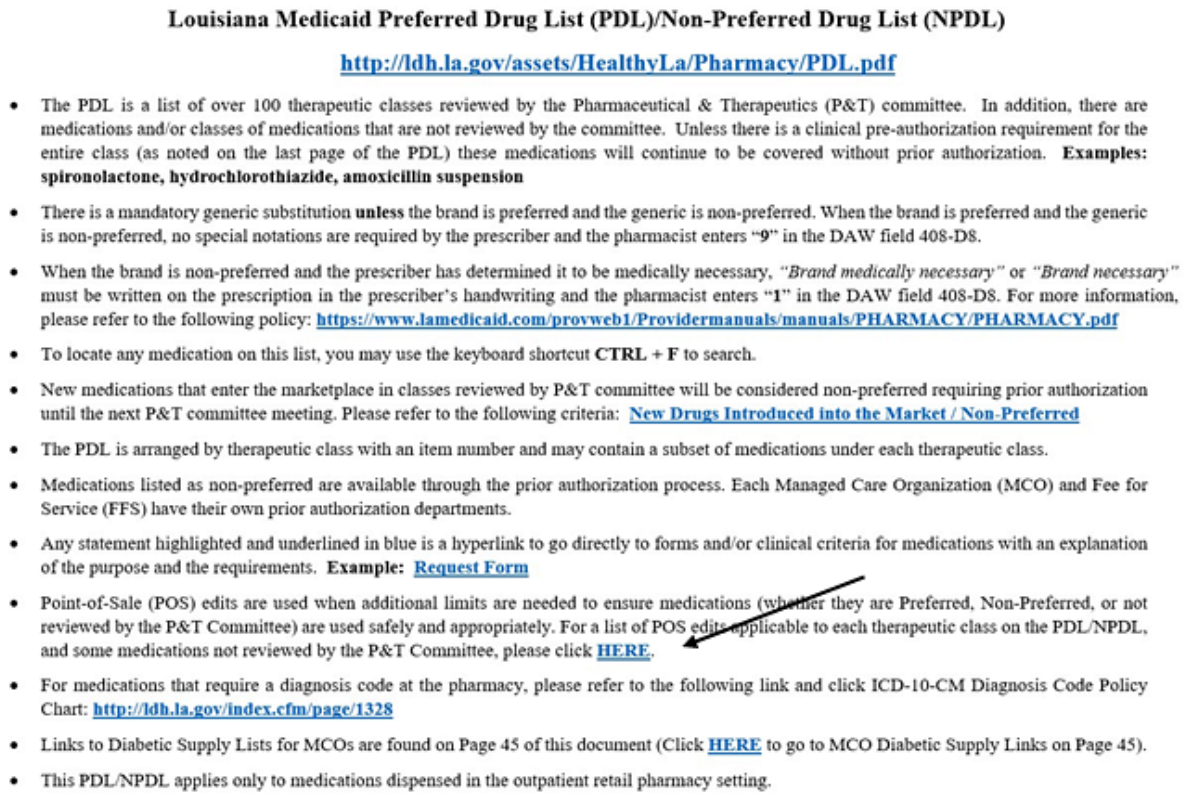
	Brand Over Generic
1	MAKENA SDV (INTRAMUSCULAR)—Brand and generic preferred
2	FOCALIN XR (ORAL)
3	COPAXONE 20 MG/ML (SUBCUTANE.)
4	TAMIFLU CAPSULE (ORAL)
5	NATROBA (TOPICAL)
6	VOLTAREN (TOPICAL) – Brand and generic preferred

	Brand Over Generic
7	XELODA (ORAL)
8	TOBRADEX SUSPENSION (OPHTHALMIC)
9	GLEEVEC (ORAL)
10	PROCENTRA (ORAL)
11	CATAPRES-TTS (TRANSDERM)
12	ALPHAGAN P 0.15% (OPHTHALMIC)
13	SUBOXONE FILM (SUBLINGUAL)
14	RENAGEL (ORAL)

Naloxone Standing Order
The Naloxone Standing Order for 2020 has been renewed by Dr. Rebekah Gee. Please refer to the Louisiana Department of Health website in January for information.

Enbrel
On January 13, 2020, Enbrel will be changed from non-preferred to preferred status.

Preferred Drug List (PDL) Cosmetic Modifications
For the January 1, 2020 PDL there will be some cosmetic modifications. The Point of Sale (POS) edits will be removed and placed into a document that can be found on the title page. See below:



Louisiana Medicaid Preferred Drug List (PDL)/Non-Preferred Drug List (NPDL)

http://ldh.la.gov/assets/HealthyLa/Pharmacy/PDL.pdf

- The PDL is a list of over 100 therapeutic classes reviewed by the Pharmaceutical & Therapeutics (P&T) committee. In addition, there are medications and/or classes of medications that are not reviewed by the committee. Unless there is a clinical pre-authorization requirement for the entire class (as noted on the last page of the PDL) these medications will continue to be covered without prior authorization. **Examples: spironolactone, hydrochlorothiazide, amoxicillin suspension**
- There is a mandatory generic substitution **unless** the brand is preferred and the generic is non-preferred. When the brand is preferred and the generic is non-preferred, no special notations are required by the prescriber and the pharmacist enters "**9**" in the DAW field 408-D8.
- When the brand is non-preferred and the prescriber has determined it to be medically necessary, *"Brand medically necessary"* or *"Brand necessary"* must be written on the prescription in the prescriber's handwriting and the pharmacist enters "**1**" in the DAW field 408-D8. For more information, please refer to the following policy: **https://www.lamedicaid.com/provweb1/Providermanuals/manuals/PHARMACY/PHARMACY.pdf**
- To locate any medication on this list, you may use the keyboard shortcut **CTRL + F** to search.
- New medications that enter the marketplace in classes reviewed by P&T committee will be considered non-preferred requiring prior authorization until the next P&T committee meeting. Please refer to the following criteria: **New Drugs Introduced into the Market / Non-Preferred**
- The PDL is arranged by therapeutic class with an item number and may contain a subset of medications under each therapeutic class.
- Medications listed as non-preferred are available through the prior authorization process. Each Managed Care Organization (MCO) and Fee for Service (FFS) have their own prior authorization departments.
- Any statement highlighted and underlined in blue is a hyperlink to go directly to forms and/or clinical criteria for medications with an explanation of the purpose and the requirements. **Example: Request Form**
- Point-of-Sale (POS) edits are used when additional limits are needed to ensure medications (whether they are Preferred, Non-Preferred, or not reviewed by the P&T Committee) are used safely and appropriately. For a list of POS edits applicable to each therapeutic class on the PDL/NPDL, and some medications not reviewed by the P&T Committee, please click **HERE**.
- For medications that require a diagnosis code at the pharmacy, please refer to the following link and click ICD-10-CM Diagnosis Code Policy Chart: **http://ldh.la.gov/index.cfm/page/1328**
- Links to Diabetic Supply Lists for MCOs are found on Page 45 of this document (Click **HERE** to go to MCO Diabetic Supply Links on Page 45).
- This PDL/NPDL applies only to medications dispensed in the outpatient retail pharmacy setting.

Below is the last page of the current PDL which lists drugs with POS edits that are not included as preferred or non-preferred. On January 1, 2020, this page will be included at the end of the POS document mentioned above. (See arrow.)

ADDITIONAL AGENTS THAT HAVE POINT-OF-SALE (POS) REQUIREMENT(S)

Click Here for Behavioral Health Agents Listed Below for Children Younger Than Six (BH) | Click Here for Agents Listed Below with POS Requirements

Acetaminophen	POS	Exjade®, Jadenu® (Deferasirox)	POS	Nucala® (Mepolizumab)	CL
Actimmune® (Interferon Gamma-1b)	POS	Exondys 51® (Eteplirsen)	CL, DX	Oralair® (Mixed Grass Allergen Extract)	POS
Alferon N® (Interferon Alfa-N3)	POS	Fabrazyme® (Agalsidase beta)	POS	Palynziq® (Pegvaliase-pqpz)	CL
Amitriptyline	BH, TD	Fasenra® (Benralizumab)	CL	Proleukin® (Aldesleukin)	POS
Amitriptyline/Chlordiazepoxide	BH	Flolan® (Epoprostenol Sodium)	POS	Protriptyline	BH, TD
Amoxapine	BH, TD	Fycompa® (Perampanel)	POS	Pulmozyme® (Dornase Alfa)	POS
Aspirin	POS	Hereditary Angioedema – Berinert®, Cinryze®, Firazyr®, Haegarda®, Kalbitor®, Ruconest®, Takhzyro™	CL	Remodulin® (Treprostinil Sodium) INJECTION	POS
Austedo® (Deutetrabenazine)	CL	**HIV Agents**	POS	Santyl® (Collagenase)	QL
Beyaz® (Drospirenone/Ethinyl Estradiol/ Levomefolate Calcium)	POS	Imipramine	BH, TD	Skyrizi® (Risankizumab-rzaa)	CL
Botox® (OnabotulinumtoxinA)	DX, QL	Increlex® (Mecasermin)	CL	Soliris® (Eculizumab)	POS
Carafate® (Sucralfate)	POS	Ingrezza® (Valbenazine)	CL	Spinraza® (Nusinersen)	CL, DX
Chlordiazepoxide/Clidinium	BH	Intron-A® (Interferon Alfa-2B Recombinant)	POS	Spravato® (Esketamine)	CL
Chlorpromazine Injectable	BH	Isotretinoin	POS	Sylatron® (Peginterferon alfa-2b)	POS
Cialis® (Tadalafil) 2.5mg, 5mg	POS	Kuvan® (Sapropterin Dihydrochloride)	CL	Synagis® (Palivizumab) Criteria & Request Form	AL, CL, DT, QL
Cinqair® (Reslizumab)	CL	Lithium	BH	Tosymra® (Sumatriptan)	POS
Clomipramine	BH, TD	Lokelma® (Sodium Zirconium Cyclosilicate)	CL	Trimipramine	BH, TD
Clonazepam Tablet	BH, BY, QL	Lorazepam Injectable	BY	Veletri® (Epoprostenol)	POS
Daraprim® (Pyrimethamine)	CL	Lumizyme® (Alglucosidase alfa)	POS	Veltassa® (Patiromer)	CL
Desipramine	BH, TD	Maprotiline	BH	Xenazine® (Tetrabenazine)	CL
Doral® (Quazepam)	MD	Mavenclad® (Cladribine)	CL	Xenical® (Orlistat)	DX, QL
Doxepin (10mg-150mg)	BH, TD	Mosquito Repellant to Decrease Zika Virus Exposure Risk FFS Notice MCO Notice	AL, DX, QL	Xeomin® (IncobotulinumtoxinA)	DX, QL
Dysport® (AbobotulinumtoxinA)	DX	Myobloc® (RimabotulinumtoxinB)	DX	Xolair® (Omalizumab)	CL
Endari® (L-Glutamine)	CL	Nexplanon® (Etonogestrel)	POS	Xyrem® (Sodium Oxybate)	CL, TD
Equetro® (Carbamazepine)	BH, BY	Nortriptyline	BH, TD	Zolgensma® (Onasemnogene Abeparvovec-xioi)	CL

Eligibility and Enrollment System Provider Bulletins

Louisiana Medicaid is publishing bi-weekly provider bulletins to address provider questions and concerns around the new eligibility and enrollment system. The information in these bulletins covers a wide range of provider issues and provider types. This and other news can be found on the web site dedicated to the new system, found here: http://ldh.la.gov/index.cfm/page/3497.

If there are topics you feel need to be covered in these public communications, please let us know by sending an email to Healthy@la.gov.

Public Notice and Comment Procedure

As of Aug. 1, 2019, a public notice and comment period is required before certain policies and procedures are adopted. Drafts will be published on LDH's website to allow for public comment, as per HB 434 of the 2019 Regular Legislative Session. This requirement applies to managed care policies and procedures, systems guidance impacting edits and payment, and Medicaid provider manuals.

In compliance with R.S. 46:460.51(15), 460.53, and 460.54, this procedure provides for a defined term, a public notice requirement, implementation of a policy for the adoption of policies and procedures, and for related matters.

http://www.ldh.la.gov/index.cfm/page/3616

PAYMENT ERROR RATE MEASUREMENT (PERM)
Reporting Year (RY) 2021 Cycle Currently Underway

Louisiana Medicaid is mandated to participate in the Centers for Medicare and Medicaid (CMS) **Payment Error Rate Measurement (PERM)** program which will assess our payment accuracy rate for the Medicaid and CHIP programs. If chosen in a random sample, your organization will soon receive a *Medical Records Request* from the CMS review contractor, AdvanceMed. This cycle measurement will review Medicaid and CHIP payments made in Reporting Year (RY) 2021: July 1, 2019 through June 30, 2020.

Please be advised that sampled providers who fail to cooperate with the CMS Review Contractor by established deadlines may be subject to sanctioning by Louisiana Medicaid Program Integrity section through the imposition of a payment recovery by means of a withholding of payment until the overpayment is satisfied, and/or a fine.

Please be reminded that providers who are no longer doing business with Louisiana Medicaid are obligated to retain recipient records for 5 years, under the terms of the Provider Enrollment Agreement.

For more information about PERM and your role as a provider, please visit the Provider link on the CMS PERM website:
http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/PERM/Providers.html

If you have any questions, please call Program Integrity at 225-219-4149.

Remittance Advice Corner

Attention Durable Medical Equipment Providers

LDH revised the Pediatric Hospital Bed Evaluation Form and published the new document on www.lamedicaid.com under forms, files and user manuals. A link to the form will be included in the DME provider manual as Appendix H, as well. The revisions to the form were made to assist providers to ensure that practitioners complete all required sections prior to submission to DXC Technology. DME providers should utilize the revised form when submitting prior authorization requests for a pediatric hospital bed.

Utilization of the previous version of the form will not result in denial, however, the form **must** be completed in its entirety in order for DXC Technology staff to determine medical necessity.

Questions regarding this message and fee for service claims should be directed to DXC Technology Provider Relations at (800) 473-2783 or (225) 924-5040.

Manual Chapter Revision Log

Manual Chapter	Section(s)	Date of Revision(s)
American Indian 638 Clinics https://www.lamedicaid.com/provweb1/Providermanuals/manuals/AI638C/American_Indian.pdf	Section 39.0 Overview Section 39.4 Reimbursement Appendix A Message For All EPSDT Eligibles And Their Parents	02/06/20
Applied Behavior Analysis https://www.lamedicaid.com/provweb1/Providermanuals/manuals/ABA/ABA.pdf	4.3 – Service Authorization Process	02/11/20
Children's Choice Waiver https://www.lamedicaid.com/provweb1/Providermanuals/manuals/CCW/CCW.pdf	14.0 Overview 14.1 Covered Services 14.2 Beneficiary Requirements 14.3 Rights and Responsibilities 14.4 Service Access and Authorization 14.5 Provider Requirements 14.6 Staffing Requirements 14.7 Record Keeping 14.9 Program Monitoring 14.11 Support Coordination 14.12 Self-Direction Service Option Appendix B Glossary Appendix D Forms	02/26/20
Hospital Services https://www.lamedicaid.com/provweb1/Providermanuals/manuals/CCW/CCW.pdf	25.3 Outpatient Services	02/05/20
Pharmacy Management Benefits https://www.lamedicaid.com/provweb1/Providermanuals/manuals/CCW/CCW.pdf	37.3 Reimbursement 37.1 Covered Services	02/06/20

Manual Chapter Revision Log

Manual Chapter	Section(s)	Date of Revision(s)
Rural Health Clinics https://www.lamedicaid.com/provweb1/Providermanuals/manuals/CCW/CCW.pdf	Table of Contents 40.0 Overview 40.1 Covered Services 40.2 Provider Requirements 40.3 Record Keeping 40.4 Reimbursement Appendix A Contact Information Appendix B Forms Appendix C Glossary Appendix D Claims Related Information	02/27/20
Supports Waiver https://www.lamedicaid.com/provweb1/Providermanuals/manuals/SW/SW.pdf	Appendix C Contact Referral Information Appendix D Forms and Links	02/05/20

Archived Manual Chapter Revision Log

Manual Chapter	Section(s)	Date of Omission(s)
American Indian 638 Clinics https://www.lamedicaid.com/provweb1/Providermanuals/manuals/AI638C/American_Indian.pdf	Section 39.0 Overview Section 39.4 Reimbursement Appendix A Message For All EPSDT Eligibles And Their Parents	02/06/20
Applied Behavior Analysis https://www.lamedicaid.com/provweb1/Providermanuals/manuals/ABA/ABA.pdf	4.3 – Service Authorization Process	02/11/20

Archived Manual Chapter Revision Log

Manual Chapter	Section(s)	Date of Omission(s)
Children's Choice Waiver https://www.lamedicaid.com/provweb1/Providermanuals/manuals/CCW/CCW.pdf	14.0 Overview 14.1 Covered Services 14.2 Beneficiary Requirements 14.3 Rights and Responsibilities 14.4 Service Access and Authorization 14.5 Provider Requirements 14.6 Staffing Requirements 14.7 Record Keeping 14.9 Program Monitoring 14.11 Support Coordination 14.12 Self-Direction Service Option Appendix B Glossary Appendix D Forms	02/26/20
Hospital Services https://www.lamedicaid.com/provweb1/Providermanuals/manuals/CCW/CCW.pdf	25.3 Outpatient Services	02/05/20
Pharmacy Management Benefits https://www.lamedicaid.com/provweb1/Providermanuals/manuals/CCW/CCW.pdf	37.3 Reimbursement 37.1 Covered Services	02/06/20
Rural Health Clinics https://www.lamedicaid.com/provweb1/Providermanuals/manuals/CCW/CCW.pdf	Table of Contents 40.0 Overview 40.1 Covered Services 40.2 Provider Requirements 40.3 Record Keeping 40.4 Reimbursement Appendix A Contact Information Appendix B Forms Appendix C Glossary Appendix D Claims Related Information	02/27/20
Supports Waiver https://www.lamedicaid.com/provweb1/Providermanuals/manuals/SW/SW.pdf	Appendix C Contact Referral Information Appendix D Forms and Links	02/05/20

For Information or Assistance, Call Us!

Provider Enrollment	(225)216-6370
Prior Authorization:	
Home Health/EPSDT – PCS	1-800-807-1320
Dental	1-866-263-6534 1-504-941-8206
DME & All Other	1-800-488-6334 (225) 928-5263
Hospital Pre-Certification	1-800-877-0666
Provider Relations	1-800-473-2783 (225) 924-5040
REVS Line	1-800-776-6323 (225) 216-(REVS)7387
Point of Sale Help Desk	1-800-648-0790 (225) 216-6381

General Medicaid Eligibility Hotline	1-888-342-6207
MMIS Claims Processing Resolution Unit	(225) 342-3855
MMIS/Recipient Retroactive Reimbursement	(225) 342-1739 1-866-640-3905
Medicare Savings Program and Medicaid Purchase Hotline	1-888-544-7996
For Hearing Impaired	1-877-544-9544
Pharmacy Hotline	1-800-437-9101
Medicaid Fraud Hotline	1-800-488-2917