Louisiana Medicaid | Provider UPDATE

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Medicaid's Provider Enrollment Portal Is Available for Provider Access

The Medicaid Provider Enrollment Portal is available again for providers to access. The portal was temporarily unavailable starting mid-January 2022 to make systems edits to enhance security. It re-launched on February 14, 2022. All providers are encouraged to visit the portal and complete the screening and enrollment process as soon as possible. Enrollment through the portal is required for all Medicaid providers, and failure to do so could result in claims denial.

To complete enrollment at lamedicaid.com, providers will need several data elements, including: Louisiana Provider ID, NPI, city, state and zip code. Providers can get this information from the invitation letter they received from Gainwell Technologies.

If a provider does not have this letter or this information, they can email LouisianaProvEnroll@gainwelltechnologies.com to request a reprinted letter be mailed. Email requests must include the provider Name and the NPI. Providers may send multiple provider requests in a single email. Reprinted letter requests will only be accepted by email. No other form of submission is accepted. Providers will receive a confirmation email from Gainwell when the submission is received. That email will include an anticipated turnaround time for the response.

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For questions or concerns, providers can reach out to Louisiana Medicaid via the following options:

- Web site: www.ldh.la.gov/medicaidproviderenrollment
- Email: LouisianaProvEnroll@gainwelltechnologies.com
- Phone: #1-833-641-2140 (Monday – Friday, between 8 a.m. and 5 p.m. CST)

Providers also can find additional information in IB 22 -4 Medicaid Provider Enrollment Portal .

Clinical Considerations of the Interchangeability Between the Various Formulations of Extended-Release Methylphenidate

Matt Mallisee, PharmD

As one of the first line treatments for attention deficit hyperactivity disorder (ADHD), one of the biggest challenges associated with extended-release methylphenidate is understanding the differences and interchangeability between the various formulations, brand names, and their respective generics available. [1] The purpose of this article is to compare the relevant clinical characteristics of each product and the effects that their different formulations have on each product's onset/duration of action and therapeutic equivalence.

Over the past 20 years, significant advances have been made in the technologies used for targeted drug delivery. This has allowed providers an expanded arsenal of therapeutic approaches for a variety of different disease states.

A number of these novel approaches have been applied towards the formulation of extended-release methylphenidate, allowing providers the ability to prescribe therapies that fit their patient's needs more precisely. The most prominent difference between these formulations resides in a drug's onset and/or duration of action. These differences stem from the various drug release systems that allow for a combination of immediate and extended-release components to exist in one dosage form. The application of the product-specific release mechanisms used may be found in Table 1. The background of these mechanisms are as follows:

- **OROS: Osmotic Controlled Release Oral Delivery System** [2]
  - Composed of an immediate release tablet coating and a controlled release active drug core
  - Controlled release of drug is driven by osmotic pressure that is generated by the outer layer of the tablet core, a semi-permeable membrane that facilitates water penetration into the core
  - Aqueous penetration of the tablet core causes the expansion of an osmotically active polymer that pushes the active drug out of a laser-drilled orifice located on one end of the tablet
  - Release is controlled by the semi-permeable membrane, therefore controlling drug delivery

- **SODAS®: Spheroidal Oral Drug Absorption System** [1,3]
  - Contains both immediate and controlled release bead technology that offers a biphasic drug delivery approach.
  - The controlled release beads contain multiple polymer layers that are degraded over time until the inner active drug layer is released, providing a second dose of drug after a given time.

- **Delexis® Platform** [1]
  - Designed to allow drugs to be dosed in the evening where no less than 95% of the drug is slowly released starting roughly 10 hours after administration.
  - Utilizes a bead microparticle with an external time and pH-dependent delayed release layer and a secondary hydrophobic extended-release layer that allows for controlled dissolution and release of the active drug core into the bloodstream.

- **Multi-Layer Release Systems** [1]
  - Utilizes a single type of bead particle separated by immediate and controlled release layers, varying in their proportional values of drug between each product.

- **Distinct Microparticle Systems** [1]
  - This platform consists of two distinct types of microparticles, one that is film-coated for delayed absorption and subsequent extended release, and another with no film-coating for immediate absorption and release.

Aside from the varying drug release mechanisms, several formulations have been developed specifically for the pediatric and adolescent demographics. These products were designed with the intent to ease the barrier of administration that can be commonly observed within this specific population via formulations for a transdermal patch, oral liquid, and orally disintegrating tablet that may offer greater flexibility for certain patients.

The variety of formulation approaches and drug release mechanisms can serve as a source of confusion for both patients and providers. This effect is particularly exacerbated by each product's listed generic name. At first glance one could easily conclude that there is no difference between generic products with the same listed name: methylphenidate extended release. This conclusion can be mistakenly made both within the same dosage form (tablets vs. tablets, for example), and across formulations (tablets vs. capsules). While it is understandable that this misconception can be easily made, it is important to note that these products can differ significantly in how their active ingredient is released over time, as well as the proportional values of immediate and extended-release relative to the total dose.

When assessing the use of different formulations/release mechanisms of the same active drug product, four distinct definitions are used: bioequivalence, pharmaceutical equivalence, pharmaceutical alternative, and therapeutic equivalence (also known as interchangeability). [4]

- **Bioequivalence:** A product is considered by the Food and Drug Administration (FDA) to be bioequivalent to a reference drug when it displays a similar pharmacokinetic profile to that of the reference drug. These pharmacokinetic parameters include but are not limited to:
    - Rate and extent of drug absorption
    - Bloodstream drug concentrations
    - Onset/Duration of action

- **Pharmaceutical Equivalence:** Pharmaceutically equivalent products may differ in release mechanism, labeling, scoring, shape, and inactive ingredients. The FDA considers drug products to be pharmaceutically equivalent if it meets three criteria.
    - They contain the same active ingredient(s)
    - They are of the same dosage form and route of administration
    - They are identical in strength or concentration

- **Pharmaceutical Alternative:** Drug products that contain the same active drug, but differ in strength, dosage form, formulation, among other characteristics.
    - Extended-release drugs are considered pharmaceutical alternatives to immediate release drugs with the same active ingredient(s)
    - A transdermal patch is considered a pharmaceutical alternative to an oral drug form in a product with the same active ingredient

- **Therapeutic Equivalence:** Drug products are only considered therapeutically equivalent when they are classified as both bioequivalent *and* pharmaceutically equivalent. Therapeutically equivalent products are considered to have the same clinical effect and safety profile when FDA labeling is followed. Generic products produced by manufacturers other than the producer of the brand name product may not always be therapeutically equivalent to their brand name if it is determined that the standards of bioequivalence are not met. The most relevant example of this is found with select manufacturer's generic product for Concerta. These manufacturers have not submitted sufficient evidence for the FDA to determine them therapeutically equivalent, and therefore are not interchangeable.

These complex variables that factor into FDA equivalency ratings can be challenging to tackle even without the additional complicating factors that relate to extended-release methylphenidate and its diverse array of release mechanisms and formulations. These products are only considered interchangeable when they are both bioequivalent and pharmaceutically equivalent; therefore, they must have the same active ingredient, pharmacokinetic profile, dose strength, dosage form, route of administration, and release mechanism.

The ability to optimize functional outcomes and achieve the individualized goals of care for each individual patient with ADHD has been significantly enhanced due to these novel release platforms. [1] Understanding the pharmacokinetic implications of the various release mechanisms of each extended-release methylphenidate product, and their impact on equivalency characterizations across this class, is a concept that is essential to delivering the best patient centered care possible.

Table 1: Extended-Release Methylphenidate Product Pharmacokinetic and Equivalence Properties

Brand Name‡ *generic name*	Dosage Form	Release Mechanism	Immediate Release	Extended/ Delayed Release	Onset of Action	Duration of Action	Equivalence Characterization*
Adhansia XR© [4,5] *methylphenidate HCl ER (XR)*	Extended-release capsules	Multi-layered beads	20%	80%	60 minutes	16 hours	N/A**
Aptensio XR© [4,5] *methylphenidate HCl ER (XR)*	Extended-release capsules	Multi-layered beads	40%	60%	60 minutes	12 hours	Interchangeable with generic(s)
Concerta© [4,6] *methylphenidate HCl ER*	Extended-release tablets	OROS	22%	78%	20-60 minutes	12 hours	Interchangeable with most generic(s)
Cotempla XR-ODT© [4,5]	Extended-release oral disintegrating tablets	Distinct microparticle components	25%	75%	60 minutes	8-12 hours	N/A**
Daytrana© [4,5]	Transdermal Patch	Adhesive based matrix transdermal system	0%	100%	120 minutes	11-12 hours	N/A**
Jornay PM™ [4,5]	Extended-release capsules	Delexis© platform	0-5%	95-100%	8-10 hours	22-24 hours	N/A**
Metadate CD© [4,6] *methylphenidate HCl ER (CD)*	Extended-release capsules	Distinct microparticle components	30%	70%	20-60 minutes	6-8 hours	Interchangeable with generic(s)
Metadate ER© [1,4] *Methylphenidate HCl ER*	Extended-release tablets	Wax-based matrix	***	***	***	8 hours	N/A**
Relexxii© [7] *Methylphenidate HCl ER*	Extended-release tablets	Osmotic pressure release similar to SODAS©	22%	78%	60 minutes	12 hours	N/A**
Ritalin LA© [1,3,4,5,6] *methylphenidate HCl ER (LA)*	Extended-release capsules	SODAS©	50%	50%	30-45 minutes	6-8 hours	Interchangeable with generic(s)
Quillichew ER© [1,4,5]	Extended-release chewable tablets	Distinct microparticle components	30%	70%	45 minutes	8-10 hours	N/A**
Quillivant XR© [4,5]	Extended-release oral suspension	Distinct microparticle components	20%	80%	45 minutes	8-12 hours	Interchangeable with generic(s)

‡Some brand name products may no longer be available

*All products are considered pharmaceutical alternatives of one another. Generic availability may vary.

**Generic product not available in marketplace

***Metadate ER immediate/extended-release tablet composition and onset of action are not available in FDA approved labeling

References:

1. Pheils J, Ehret MJ. Update on methylphenidate and dexmethylphenidate formulations for children with attention-deficit/hyperactivity disorder. *American Journal of Health-System Pharmacy*. 2021;78(10):840-849. doi:10.1093/ajhp/zxab069
2. Concerta (methylphenidate HCL) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; June 2021. HIGHLIGHTS OF PRESCRIBING INFORMATION (janssenlabels.com)
3. Ritalin LA (methylphenidate hydrochloride) [package insert]. Gainesville, GA: Novartis Pharmaceuticals Corporation; January 2017. Label for Ritalin LA (fda.gov)
4. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Science, Office of Generic Drugs. 2021.
5. Steingard R, Taskiran S, Connor DF, Markowitz JS, Stein MA. New formulations of stimulants: An update for clinicians. *Journal of Child and Adolescent Psychopharmacology*. 2019;29(5):324-339. doi:10.1089/cap.2019.0043
6. Jain R, Katic A. Current and investigational medication delivery systems for treating attention-deficit/hyperactivity disorder. *The Primary Care Companion For CNS Disorders*. August 2016. doi:10.4088/pcc.16r01979
7. Relexxii (methylphenidate hydrochloride extended-release tablets, USP) [package insert]. Alpharetta, GA: Vertical Pharmaceuticals, LLC; November 2021 DailyMed - RELEXXII- methylphenidate hydrochloride tablet, extended release (nih.gov)

Louisiana Developmental Screening Toolkit

As of January 1, 2021, Louisiana Medicaid providers can receive reimbursement for developmental screening, autism screening, and perinatal depression screening. **The Louisiana Department of Health's Developmental Screening Toolkit** was created to help clinics integrate these screening into their day-to-day practice. The toolkit consists of step-by-step information contained in webpages, instructional videos, and downloadable worksheets. It is designed to house all of the information and tools you will need to put the Louisiana Developmental Screening Guidelines into practice in one, convenient spot.

The toolkit uses a quality improvement framework, which allows providers to systematically improve the way health care is delivered to the families they serve. The information and QI framework for this toolkit is based on clinical guidelines from the American Academy of Pediatrics (AAP), other national toolkits, and lessons learned from the field. It is designed to improve efficiency, patient safety, and clinical outcomes. It can be used as an **American Board of Pediatrics MOC-4** project for providers who are leading the QI efforts.

Check out the Developmental Screening Toolkit at **ldh.la.gov/DevScreenToolkit** to learn more.

New Medicaid Eligibility Group Covers COVID-19 Testing for Uninsured Patients

Per the Families First Coronavirus Response Act and the Coronavirus Aid, Relief, and Economic Security Act, Louisiana Medicaid has expanded coverage to include COVID-19 testing for uninsured individuals for the duration of the federally declared public health emergency. Coverage is limited to COVID-19 testing and related office visits for uninsured Louisiana residents. No treatment costs are covered under this program.

The new benefit is provided through Medicaid fee-for-service and not Healthy Louisiana through a managed care organization. Providers must be a Medicaid enrolled provider and must be enrolled before services are provided. Providers not enrolled as a Medicaid provider with Gainwell Technologies will need to complete a temporary emergency application with Medicaid's fiscal intermediary, Gainwell Technologies, to be paid for testing and testing related services for the uninsured. Providers will be required to self-attest on the uninsured individual's application to Medicaid that they are not also billing the Department of Health and Human Services (HHS) or the Health Resources and Services Administration (HRSA) for the same services. You also may not bill on any contract with the Louisiana

Department of Health to provide COVID-19 testing for these patients. If Medicaid identifies other third party coverage is available (e.g., Medicare, private insurance), Medicaid will not cover the services.

For additional guidance, visit Medicaid's provider web page for COVID-19 testing coverage for uninsured individuals. The site contains billing information, a detailed provider guide, frequently asked questions for providers, and the simplified application patients can fill out to determine if they are eligible for coverage.

PHARMACY FACTS

Program Updates from Louisiana Medicaid

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

January 10, 2022

Provider Enrollment Portal

All providers who file claims with Louisiana Medicaid, including pharmacy providers, must enroll in the new Medicaid Provider Enrollment Portal **to continue getting reimbursed**.

Enrollment is mandated by CMS and applies to any provider that provides care to Medicaid members, which includes current managed care organization (MCO) only providers, Dental Benefits Program Manager (DBPM) providers, Coordinated System of Care (CSoC) providers, existing fee-for-service providers, and any new providers enrolling for the first time. All providers must login and submit an enrollment through the portal at www.lamedicaid.com by March 31, 2022.

To better support providers, **Louisiana Medicaid is conducting a provider enrollment drive, focused on pharmacy providers, from January 24 through February 21, 2022.** During this time, we will be working with your provider associations to encourage enrollment and provide you with additional resources.

More information is available at www.ldh.la.gov/medicaidproviderenrollment, including previously recorded webinars, a provider manual and frequently asked questions about the portal. If you have further questions about the portal or your www.lamedicaid.com account, please email LouisianaProvEnroll@gainwelltechnologies.com or call 833-641-2140, Monday – Friday between the hours of 8 a.m. and 5 p.m. CST.

Preferred Drug List (PDL) Update

The updated PDL that was implemented January 1, 2022 has been posted at https://ldh.la.gov/assets/HealthyLa/Pharmacy/PDL.pdf.

There are two new therapeutic classes added to the PDL including:

- Immunomodulators, Lupus.
- Ophthalmics, Cystinosis.

We have received questions about brand products that are preferred when the less-expensive generic version is non-preferred. For Medicaid to make a drug payable, the drug manufacturer is required by CMS to supply a rebate to Medicaid states. The rebate amount varies depending on the drug designation (brand or generic) and is adjusted due to the rate of price increase (CPI-U). Sometimes, the brand drug's net cost to the state is less than the generic version. LDH limits how many brand drugs are preferred over generics. The rebate program was designed to ensure Medicaid the best price, therefore saving taxpayer dollars.

Remittance Advice Corner

Louisiana Medicaid 2021 1099's

Louisiana Medicaid 2021 1099's will be distributed by U.S. Mail on or before January 31, 2022. Electronic copies are now available for download by going to the Louisiana Medicaid website, www.lamedicaid.com, Secure Portal, application link, Online 1099. If replacement copies or additional copies are needed, providers must print them from tl website. If you feel there is an error on your 1099, please contact Gainwell Provider Enrollment at 225-216-6370. Prio year 1099's will be stored in the archive on www.lamedicaid.com.

Medicaid 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. Public Comments for the listed policies and procedures can be left at the link below.

- Louisiana Medicaid (Title XIX) State Plan and Amendments;
- Louisiana Medicaid Administrative Rulemaking Activity;
- Medicaid Provider Manuals;
- Contract Amendments;
- Managed Care Policies & Procedures; and
- Demonstrations and Waivers.

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

Manual Chapter Revision Log

Manual Chapter	Section(s)	Date of Revision(s)
Behavioral Health Behavioral Health	• Appendix A – Forms and Links	02/15/22
	• Table of Contents • Section 2.3 – Outpatient Services – Individual Placement and Support Services • Section 2.3 – Outpatient Services – Personal Care Services	02/21/22
	• Table of Contents • Section 2.3 – Outpatient Services – Crisis Services – Crisis Response Services for Adults • Appendix B – Glossary and Acronyms • Appendix D – Approved Curriculum Equivalency Standards	02/23/22

Manual Chapter Revision Log, Continued

Manual Chapter	Section(s)	Date of Revision(s)
	• Section 2.0 – Overview • Section 2.2 – Bed Based Services – Therapeutic Group Homes • Section 2.2 – Bed Based Services – Psychiatric Residential Treatment Facilities • Section 2.3 – Outpatient Services – FQHC and RHC • Section 2.3 – Outpatient Services – Peer Support • Section 2.3 – Outpatient Services – Outpatient Therapy by Licensed Practitioners • Section 2.4 – Addiction Services • Section 2.5 – Coordinated System of Care (CSoC) • Section 2.6 – Record Keeping • Appendix C – Medical Necessity and EPSDT Exceptions Policy • Appendix E-1 – Evidence Based Practices – Assertive Community Treatment (ACT) • Appendix E-2 – Evidence Based Practices – Functional Family Therapy (FFT) and Functional Therapy – Child Welfare (FFT-CW) • Appendix E-3 – Evidence Based Practices – Homebuilders • Appendix E-4 – Evidence Based Practices – Multi-Systemic Therapy (MST) • Appendix E-5 – Evidence Based Practices – Child Parent Psychotherapy (CPP) • Appendix E-6 – Evidence Based Practices – Parent Child Interaction Therapy (PCIT) • Appendix E-7 – Evidence Based Practices – Preschool PTSD Treatment and Youth PTSD Treatment • Appendix E-8 – Evidence Based Practices – Triple P – Standard Level 4 • Appendix E-9 – Evidence Based Practices – Trauma-Focused Cognitive Behavioral Therapy (TF-CBT) • Appendix E-10 – Evidence Based Practices – Eye Movement Desensitization and Reprocessing (EMDR) Therapy • Appendix F – CSoC Wraparound Model • Appendix G – Standardized Assessments for Members Receiving CPST and PSR	02/25/22

Manual Chapter Revision Log, Continued

Manual Chapter	Section(s)	Date of Revision(s)
Dental Services Dental Services	• Section 16.5 – EPSDT – Covered Services • Appendix A – EPSDT – Fee Schedule	02/08/22
	• Section 16.0 – Overview • Section 16.1 – Provider Requirements • Section 16.2 – Claims Related Information • Section 16.3 – Beneficiary Eligibility Requirements • Section 16.5 – EPSDT – Covered Services • Section 16.6 – EPSDT – Non-Covered Services • Section 16.7 – EPSDT - Prior Authorization • Section 16.9 – Adult Denture Program - Covered Services • Section 16.10 – Adult Denture Program – Non-Covered Services • Section 16.11 – Adult Denture Program – Prior Authorization • Appendix B – Adult Denture Program – Fee Schedule • Appendix D – Adjustment/Void Forms and Instructions • Appendix E – Dental Periodicity Schedule • Appendix F – Claim Dental Simplification Process • Appendix G – Prior Authorization Checklist	02/15/22
Family Planning Clinics Family Planning Clinics	• Section 33.0 – Overview • Section 33.1 – Covered Services • Section 33.2 – Beneficiary Requirements • Section 33.3 – Provider Requirements • Section 33.4 – Claims Related Information	02/03/22
Hospice Hospice	• Section 24.2 – Election of Hospice • Section 24.3 – Covered Services • Section 24.4 - Reserved • Section 24.5 - Provider Requirements • Section 24.6 - Prior Authorization Process • Section 24.7 - Hospice Revocation and Discharge • Section 24.8 - Record Keeping • Section 24.9 - Reimbursement • Section 24.10 - Claims Related Information • Section 24.11 - Program Monitoring • Section 24.12 - Appeals • Section 24.13 - Reserved • Appendix C - Hospice Diagnosis Codes • Appendix E - UB-04 Form and Instructions	02/07/22

Manual Chapter Revision Log, Continued

Manual Chapter	Section(s)	Date of Revision(s)
Medical Transportation Medical Transportation	• Section 10.0 - Overview • Section 10.1 – Covered Services • Section 10.2 – Scheduling and Dispatching • Section 10.3 – Provider Requirements • Section 10.4 – Provider Responsibilities • Section 10.5 – Record Keeping • Section 10.7 – Ambulance Overview • Section 10.8 – Emergency Ambulance Transportation • Section 10.9 – Non-Emergency Ambulance Transportation (NEAT) • Section 10.10 – Air Ambulance • Section 10.12 – Ambulance – Return Trips and Transfers • Section 10.13 – Ambulance – Claims and Encounters • Section 10.14 – Record Retention • Section 10.15 – Appendixes • Section 10.15.1 – Contact Information	02/03/22
New Opportunities Waiver (NOW) New Opportunities Waiver (NOW)	Section 32.8 – Record Keeping	02/11/22
Professional Services Professional Services	• Table of Contents • Section 5.1 – Covered Services – Sinus Procedures	02/10/22
Residential Options Waiver (ROW) Residential Options Waiver (ROW)	Section 38.8 – Record Keeping	02/11/22

For Information or Assistance, Call Us!

Provider Relations	1-800-473-2783 (225) 294-5040 Medicaid Provider Website	General Medicaid Eligibility Hotline	1-888-342-6207
Prior Authorization: Home Health/EPSDT – PCS Dental	 1-800-807-1320 1-855-702-6262 MCNA Provider Portal	MMIS Claims Processing Resolution Unit MMIS Claims Reimbursement	(225) 342-3855
DME & All Other	1-800-488-6334 (225) 928-5263	MMIS/Recipient Retroactive Reimbursement MMIS Claims Reimbursement	(225) 342-1739 1-866-640-3905
Hospital Pre-Certification	1-800-877-0666		
REVS Line	1-800-776-6323 (225) 216-(REVS)7387 REVS Website	Medicare Savings Medicare Provider Website	1-888-544-7996
Point of Sale Help Desk	1-800-648-0790 (225) 216-6381	For Hearing Impaired	1-877-544-9544
		Pharmacy Hotline Medicaid Pharmacy Benefits	1-800-437-9101
		Medicaid Fraud Hotline Report Medicaid Fraud	1-800-488-2917