

FDA Drug Safety Communications

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Human Papillomavirus (HPV) Vaccine

The Centers for Disease Control and Prevention (CDC) recommends two doses of HPV vaccine for all adolescents (both male and female) at age 11 to 12

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HPV and Cancer

- Genital human papillomavirus (HPV) is the most common sexually transmitted infection in the United States. More than 40 HPV types can infect the genital areas of men and women, including the skin of the penis, vulva (area outside the vagina), and anus, and the linings of the vagina, cervix, and rectum. These types can also infect the lining of the mouth and throat.
- Every year in the United States, 35,900 women and men are estimated to be diagnosed with a cancer caused by HPV infection.
- Although cervical cancer is the most well-known of the cancers caused by HPV, there are five other types of HPV cancer, including the following:
 - cervical precancer
 - oropharyngeal cancer
 - anal cancer
 - vulvar and vagina cancer
 - penile cancer
- Cervical cancer is the only type of HPV cancer with a recommended screening test to detect it at an early stage. The other types of HPV cancers may not be detected until they cause health problems.
- HPV vaccination could prevent more than 90% of cancers caused by HPV, estimated to be 33,000 cases every year, from ever developing.
- Even with screening, HPV causes 11,000 cases of cervical cancer each year in the U.S.

- Every year, 4,000 women die of cervical cancer.
- There are an estimated 196,000 cervical precancers cases each year in the U.S. Treatment for cervical cancers and precancers can limit women’s ability to have children.
- Every year in the U.S., there are:
 - 14,000 oropharyngeal cancer cases
 - 6,500 anal cancer cases
 - 3,500 vulvar and vaginal Cancer cases
 - 900 penile cancer cases

HPV Vaccine for 9 to 14 year Olds

- A 2-dose schedule is recommended for people who get the first dose before their 15th birthday. In a 2-dose series, the second dose should be given 6–12 months after the first dose (0, 6–12 month schedule).
- The minimum interval is 5 months between the first and second dose. If the second dose is administered after a shorter interval, a third dose should be administered a minimum of 5 months after the first dose and a minimum of 12 weeks after the second dose.
- If the vaccination schedule is interrupted, vaccine doses do not need to be repeated (no maximum interval).
- Immunogenicity studies have shown that 2 doses of HPV vaccine given to 9–14 year-olds at least 6 months apart provided as good or better protection than 3 doses given to older adolescents or young adults.

HPV Vaccine for 15 to 26 year Olds

- A 3-dose schedule is recommended for people who get the first dose on or after their 15th birthday, and for people with certain immunocompromising conditions.
- In a 3-dose series, the second dose should be given 1–2 months after the first dose, and the third dose should be given 6 months after the first dose (0, 1–2, 6 month schedule).
- The minimum intervals are 4 weeks between the first and second dose, 12 weeks between the second and third doses, and 5 months between the first and third doses. If a vaccine dose is administered after a shorter interval, it should be re-administered after another minimum interval has elapsed since the most recent dose.
- If the vaccination schedule is interrupted, vaccine doses do not need to be repeated (no maximum interval).

Five Ways to Boost HPV Vaccination Rates

- **Bundle your recommendation** – Bundle your recommendation for all adolescent vaccines, including HPV vaccine, in the same way, on the same day. You can start the vaccine discussion with, “Now that your child is 11, he/she needs three vaccines to help protect against meningitis, HPV cancers, and whooping cough. We’ll give these shots during today’s visit. Do you have any questions about these vaccines?”

- **Ensure a consistent message.** – All of your office staff should receive training on how to successfully communicate with parents and patients about HPV vaccination. Starting with the front office, make sure that everyone is on the same page when it comes to proper vaccination practices, recommendations, and how to answer parents’ questions.
- **Use every opportunity to vaccinate.** – Establish a policy to check patients’ immunization status at every visit and always recommend and administer vaccines your patients need. Call to remind families about getting vaccines if they fall behind or need follow-up doses to complete the series. Develop a process where all clinicians in your practice compare HPV vaccination rates to rates of meningococcal and Tdap vaccination.
- **Provide personal examples.** – Providing personal examples of how you support vaccinations for your family members shows you believe they are important. Share how you recommended or administered HPV vaccine for your own children, grandchildren, nieces, or nephews. Sharing your personal experience may make parents more comfortable in their decision to vaccinate their child.
- **Effectively answer questions.** – Learn how to answer some of parents’ most common questions about HPV vaccine. Be prepared to answer parents’ questions succinctly, accurately, and empathetically by using terms that they understand. A parent will often accept your explanations if presented with their children’s best interests in mind.

Answering Parents’ Questions about HPV Vaccine

Why does my child need a vaccine to prevent HPV?

Some HPV infections can cause cancer, but we can protect your child from these cancers by receiving the HPV vaccine.

Is my child really at risk for HPV?

HPV is a very common infection in women and men that can cause cancer. Starting the vaccine series today will help protect your child from the cancers and diseases caused by HPV.

Why do adolescents need HPV vaccine at such a young age?

Vaccines protect your child before they are exposed to a disease. That’s why we give the HPV vaccine earlier rather than later, to protect them long before they are ever exposed.

Also, if your child gets the shot now, they will only need two doses. If you wait until your child is older, he/she may end up needing three shots.

Why do boys need the HPV vaccine?

HPV vaccination can help prevent future infections that can lead to cancers of the penis, anus, and back of the throat in men.

How do you know the HPV vaccine works?

Studies continue to prove HPV vaccination works extremely well, decreasing the number of infections and HPV precancers in young people since it has been available. HPV vaccination is preventing cancer-causing infections and precancers.

For example, among teen girls, infections with HPV types that cause most HPV cancers and genital warts have dropped 86 percent.

Is HPV vaccination safe?

Over 12 years of monitoring and research have shown that HPV vaccination is very safe and effective. Like all vaccines, there is ongoing monitoring of HPV vaccine to ensure it is safe and effective.

For additional resources regarding HPV vaccination, healthcare providers may visit [CDC Human Papillomavirus \(HPV\)](#).

Reference: [Centers for Disease Control and Prevention \(CDC\) -Human Papillomavirus \(HPV\)](#)

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 will need to complete a [temporary emergency application](#) with Medicaid's fiscal intermediary, Gainwell, 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>.

December 18, 2020

Vaccine

Medicaid is working to make both the Pfizer and Moderna COVID vaccines payable; more information is forthcoming. The Pfizer vaccine was granted Emergency Use Authorization (EUA) on Friday, December 11, 2020. Click here to read about the vaccine and be prepared when the time comes to vaccinate recipients. Medicaid will reimburse the Medicare rates for administration (1st dose = \$15.92 and 2nd dose = \$26.68).

Louisiana Medicaid Annual Recertification

Annual recertification forms are going out this month. Louisiana Medicaid will allow three months to complete the paper form or the editable PDF version that was sent by email. The deadline to submit the requested recertification documents is March 31, 2021. If you have additional questions or concerns, you may contact Roderick Anderson at roderick.anderson@la.gov or call the Pharmacy Help Desk at (800) 648-0790. Preferred Drug List (PDL) Updates (<http://ldh.la.gov/assets/HealthyLa/Pharmacy/PDL.pdf>) The new PDL will go into effect on January 1, 2021. There are 12 new therapeutic classes added to the PDL. Those classes include:

- Anthelmintics
- Anti-Allergens, Oral
- Anticonvulsants
- Botulinum Toxins
- Enzyme Replacements
- Idiopathic Pulmonary Fibrosis
- Immune Globulins
- Immunomodulators, Asthma
- Methotrexate
- Movement Disorders
- Sickle Cell Anemia Treatments
- Thrombopoiesis Stimulating Proteins

New Diabetic Supply Quantity Link (PDL, page 1)

DIABETIC SUPPLY LIST LINKS BY PLAN	Prior Authorization Information Phone Numbers for MCOs and FFS
AETNA	Aetna Better Health of Louisiana 1-855-242-0802
AMERIHEALTH CARITAS LA	AmeriHealth Caritas Louisiana 1-800-684-5502
HEALTHY BLUE	Healthy Blue 1-844-521-6942
LOUISIANA HEALTHCARE CONNECTIONS	Louisiana Healthcare Connections 1-888-929-3790
UNITEDHEALTHCARE	UnitedHealthcare 1-800-310-6826
Fee-for-Service (FFS) Louisiana Legacy Medicaid 1-866-730-4357	
Click this Link to View Quantity Limits for Diabetic Test Strips and Lancets for FFS and All MCOs	

New Medically Necessary Criteria Link (First Page of PDL)

- For the request of clinical overrides for the use of medications outside of the established Point-of-Sale edits, such as diagnosis and quantity limits, please refer to the following criteria: [Medically Necessary](#)

Drugs highlighted in yellow indicate a new addition or a change in status.

Cetirizine Solution RX (1 mg/mL) (Generic)	Cetirizine Capsule OTC (Generic)
Cetirizine Tablet OTC (Generic)	Cetirizine Chewable Tablet OTC (Generic)
Levocetirizine Tablet OTC (Generic)	Cetirizine 5 mg/5 mL Solution OTC (Generic)
Levocetirizine Tablet (Generic)	Desloratadine Tablet (Generic; Clarinex®)

Remittance Advice Corner

Louisiana Medicaid 2020 1099s

Louisiana Medicaid 2020 1099s will be distributed by U.S. Mail on or before January 31, 2021. Electronic copies are now available for download by going to the Louisiana Medicaid web site, www.lamedicaid.com, Secure Portal, application link, Online 1099. If replacement copies or additional copies are needed, providers must print them from the web site. If you feel there is an error on your 1099, please contact Gainwell Provider Enrollment at 225-216-6370. Prior 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.

- 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.

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

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

Manual Chapter Revision Log

Manual Chapter	Section(s)	Date of Revision(s)
Applied Behavior Analysis Applied Behavior Analysis	4.1 Covered Services 4.4 Provider Requirements	01/26/21
Behavioral Health Services Behavioral Health Services Manual Chapter	2.0 Overview 2.2 Bed Based Services – Psychiatric Residential Treatment Facilities and Therapeutic Group Homes 2.3 Outpatient Services 2.4 OTP - Addiction Appendix F CSoC Wraparound	01/05/21
End Stage Renal Disease End Stage Renal Disease	17.1 Covered Services Appendix A Contact Information	01/22/21
Hospital Services Hospital Services	25.2 Inpatient Services – Donor Human Milk	01/01/21
Independent Laboratories Independent Laboratories	27.0 Overview 27.1 Covered Services 27.2 Provider Requirements 27.3 Reimbursement Appendix A Fee Schedule Appendix B Contact Information	01/23/21
Medical Transportation Medical Transportation	Title Page Table of Contents 10.0 Non –Emergency Transportation Overview 10.1 Covered Services 10.2 Scheduling and Authorization 10.3 Provider Requirements 10.4 Provider Responsibilities 10.5 Record Keeping 10.6 Claims and Encounters 10.7 Ambulance Overview 10.8 Emergency Ambulance Transportation 10.9 Non-Emergency Ambulance 10.10 Air Ambulance 10.11 Ambulance Memberships 10.12 Return Trips and Transfers 10.13 Claims and Encounters 10.14 Record Retention 10.5 Appendixes 10.15.1 Contact Information	01/11/21

Manual Chapter Revision Log (cont.)

Manual Chapter	Section(s)	Date of Revision(s)
Pharmacy Benefits Management Services Pharmacy Benefits Management Services	37.1 Covered Services	01/05/21
Professional Services Professional Services	5.1 Covered Services – Lab & Radiology	01/22/21

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