John Bel Edwards
GOVERNOR

Dr. Courtney N. Phillips
SECRETARY

State of Louisiana

Louisiana Department of Health
Office of the Secretary

VIA ELECTRONIC MAIL ONLY

January 19, 2022

Todd McMillion, Director
Division of Reimbursement Review
Financial Management Group
Center for Medicaid & CHIP Services
Centers for Medicare and Medicaid Services
233 North Michigan Ave., Suite 600
Chicago, Illinois 60601

Dear Mr. McMillion:

RE: LA SPA TN 21-0025
Federally Qualified Health Centers and Rural Health Clinics
Alternative Payment Methodology for COVID-19 Monoclonal Treatment

Please refer to our proposed Medicaid State Plan amendment (SPA) submitted under transmittal number (TN) 21-0025 with a proposed effective date of September 1, 2021. This SPA seeks approval to establish an alternative payment methodology for Federally Qualified Health Centers (FQHC) and Rural Health Clinics (RHC) for COVID-19 monoclonal treatment.

We are providing the following in response to your request for additional information (RAI) dated December 21, 2021.

Section E – Payment:

1. Please submit the responses to the standard funding questions.

   LDH RESPONSE:
   Please see attached responses to the standard funding questions.

2. Please clarify whether the services are already part of FQHC services and are covered by the PPS, or not.

LDH RESPONSE:
The FDA approved the first monoclonal antibody treatment in 1986. Historically, these monoclonal antibody treatments were performed in a hospital or infusion center setting. Based on this historical data, the State is of the belief that COVID-19 treatment was not included in the original prospective payment system (PPS) calculation.

3. Please clarify whether, even if the services would be covered by the PPS, the visits during which the services are provided are a billable encounter.

LDH RESPONSE:
Yes. The visit during which the services are provided is considered a billable encounter if an evaluation and management procedure code is included as a detailed line.

4. Please clarify whether, even if the services are covered by the PPS, the State purpose is to raise payment to FQHCs to reflect additional costs of certain COVID-19 treatments.

LDH RESPONSE:
COVID-19 monoclonal treatment visits are outside of the costs already paid under the PPS rates and are needed in order to address the unique public health emergency from December 23, 2020 to present. The reimbursement rates for treatment-only visits will be outside of the PPS rate and will be based on the Medicare cost for monoclonal antibody treatment.

5. Please refer to the approved language in Section E from LA#21-0013 SPA. Furthermore, please replace administration of vaccines language with monoclonal antibodies language.

Below is the approved language from LA#21-0013:

During the statewide COVID-19 PHE, Louisiana Medicaid will establish an alternative payment methodology (APM) for Federally Qualified Health Centers and Rural Health Clinics to receive reimbursement for COVID-19 vaccine only visits at the Medicare rate. Payments under this APM are to cover the additional costs associated with the administration of COVID-19 vaccines by FQHCs/RHCs during COVID-19 vaccine-only visits as the PPS cost base for FQHCs/RHCs did not include these costs. The payments for the vaccine-only visits provide a needed supplement to FQHCs/RHCs' reimbursement during this public health emergency. The supplemental amounts made under this APM are in addition to the Prospective Payment System (PPS) paid to FQHCs/RHCs for an encounter. The amount in total paid to FQHC and RHC providers is at least their provider-specific PPS rate.

Reimbursement will start with dates of services on December 23, 2020, and continue through the end of the Federal PHE.

Payments made to the FQHCs/RHCs under this APM will be made per submitted claim for a COVID-19 vaccine only visit, which will be reimbursed at the Medicare rate. When the COVID-19 vaccine is administered as part of an otherwise billable FQHC/RHC encounter per Attachment 4.19-B, the encounter is reimbursed under the existing PPS/APM per Attachment 4.19-B, and no separate reimbursement will be made.

FQHC and RHC providers must agree to receive the APM.

LDH RESPONSE:
The language has been replaced. Please see the attached revised LA Disaster Relief SPA pages 6, 7 and 8.

Please consider this a formal request to begin the 90-day clock. We trust this additional information will result in the approval of the pending SPA. We look forward to negotiating with CMS to ensure approval.

As always, we appreciate CMS' assistance in resolving these issues. If further information is required, you may contact Karen H. Barnes at Karen.Barnes@la.gov or by phone (225) 342-3881.

Sincerely,

Patrick Gillies
Medicaid Executive Director

PG:KHB:KS

Attachments (2)

c: Karen H. Barnes
Tobias Griffin
Monica Neiman
Tamara Sampson

Section 7 – General Provisions
7.4.1 Medicaid Disaster Relief for the COVID-19 National Emergency

On March 13, 2020, the President of the United States issued a proclamation that the COVID-19 outbreak in the United States constitutes a national emergency by the authorities vested in him by the Constitution and the laws of the United States, including sections 201 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.), and consistent with section 1135 of the Social Security Act (Act). On March 13, 2020, pursuant to section 1135(b) of the Act, the Secretary of the United States Department of Health and Human Services invoked his authority to waive or modify certain requirements of titles XVIII, XIX, and XXI of the Act as a result of the consequences COVID-19 pandemic, to the extent necessary, as determined by the Centers for Medicare & Medicaid Services (CMS), to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the respective programs and to ensure that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of such requirements as a result of the COVID-19 pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse. This authority took effect as of 6PM Eastern Standard Time on March 15, 2020, with a retroactive effective date of March 1, 2020. The emergency period will terminate, and waivers will no longer be available, upon termination of the public health emergency, including any extensions.

The State Medicaid agency (agency) seeks to implement the policies and procedures described below, which are different than the policies and procedures otherwise applied under the Medicaid state plan, during the period of the Presidential and Secretarial emergency declarations related to the COVID-19 outbreak (or any renewals thereof), or for any shorter period described below:

N/A

NOTE: States may not elect a period longer than the Presidential or Secretarial emergency declaration (or any renewal thereof). States may not propose changes on this template that restrict or limit payment, services, or eligibility, or otherwise burden beneficiaries and providers.

Request for Waivers under Section 1135

_X_ The agency seeks the following under section 1135(b)(1)(C) and/or section 1135(b)(5) of the Act:

a. __ SPA submission requirements – the agency requests modification of the requirement to submit the SPA by March 31, 2020, to obtain a SPA effective date during the first calendar quarter of 2020, pursuant to 42 CFR 430.20.

b. _X_ Public notice requirements – the agency requests waiver of public notice requirements that would otherwise be applicable to this SPA submission. These requirements may include those specified in 42 CFR 440.386 (Alternative Benefit Plans),

This SPA is in addition to Louisiana's approved Medicaid Disaster Relief SPAs and does not supersede any provisions in those SPAs.

42 CFR 447.57(c) (premiums and cost sharing), and 42 CFR 447.205 (public notice of changes in statewide methods and standards for setting payment rates).

c. _X_ Tribal consultation requirements – the agency requests modification of tribal consultation timelines specified in [Louisiana] Medicaid state plan, as described below:

To address the COVID-19 public health emergency, the State respectfully requests to modify the tribal consultation process by eliminating the number of notification days before submission of the SPA and/or conducting consultation after submission of the SPA.

Section A – Eligibility

1. ___ The agency furnishes medical assistance to the following optional groups of individuals described in section 1902(a)(10)(A)(ii) or 1902(a)(10)(c) of the Act. This may include the new optional group described at section 1902(a)(10)(A)(ii)(XXIII) and 1902(ss) of the Act providing coverage for uninsured individuals.

2. _____The agency furnishes medical assistance to the following populations of individuals described in section 1902(a)(10)(A)(ii)(XX) of the Act and 42 CFR 435.218:

   a. _____ All individuals who are described in section 1905(a)(10)(A)(ii)(XX)

      Income standard: _____

      -or-

   b. _____ Individuals described in the following categorical populations in section 1905(a) of the Act:

      Income standard: _____

3. _____ The agency applies less restrictive financial methodologies to individuals excepted from financial methodologies based on modified adjusted gross income (MAGI) as follows.

   Less restrictive income methodologies:

   Less restrictive resource methodologies:

This SPA is in addition to Louisiana's approved Medicaid Disaster Relief SPAs and does not supersede any provisions in those SPAs.

4. ___The agency considers individuals who are evacuated from the state, who leave the state for medical reasons related to the disaster or public health emergency, or who are otherwise absent from the state due to the disaster or public health emergency and who intend to return to the state, to continue to be residents of the state under 42 CFR 435.403(j)(3).

5. ___ The agency provides Medicaid coverage to the following individuals living in the state, who are non-residents:

6. __ The agency provides for an extension of the reasonable opportunity period for non-citizens declaring to be in a satisfactory immigration status, if the non-citizen is making a good faith effort to resolve any inconsistences or obtain any necessary documentation, or the agency is unable to complete the verification process within the 90-day reasonable opportunity period due to the disaster or public health emergency.

Section B – Enrollment

1. _____ The agency elects to allow hospitals to make presumptive eligibility determinations for the following additional state plan populations, or for populations in an approved section 1115 demonstration, in accordance with section 1902(a)(47)(B) of the Act and 42 CFR 435.1110, provided that the agency has determined that the hospital is capable of making such determinations.

2. _____ The agency designates itself as a qualified entity for purposes of making presumptive eligibility determinations described below in accordance with sections 1920, 1920A, 1920B, and 1920C of the Act and 42 CFR Part 435 Subpart L.

3. _____ The agency designates the following entities as qualified entities for purposes of making presumptive eligibility determinations or adds additional populations as described below in accordance with sections 1920, 1920A, 1920B, and 1920C of the Act and 42 CFR Part 435 Subpart L. Indicate if any designated entities are permitted to make presumptive eligibility determinations only for specified populations.

This SPA is in addition to Louisiana's approved Medicaid Disaster Relief SPAs and does not supersede any provisions in those SPAs.

4. _____ The agency adopts a total of _____ months (not to exceed 12 months) continuous eligibility for children under age enter age _____ (not to exceed age 19) regardless of changes in circumstances in accordance with section 1902(e)(12) of the Act and 42 CFR 435.926.

5. ____ The agency conducts redeterminations of eligibility for individuals excepted from MAGI-based financial methodologies under 42 CFR 435.603(j) once every _____ months (not to exceed 12 months) in accordance with 42 CFR 435.916(b).

6. _____ The agency uses the following simplified application(s) to support enrollment in affected areas or for affected individuals (a copy of the simplified application(s) has been submitted to CMS).

    a. _____ The agency uses a simplified paper application.

    b. _____ The agency uses a simplified online application.

    c. _____ The simplified paper or online application is made available for use in call-centers or other telephone applications in affected areas.

Section C – Premiums and Cost Sharing

1. __ The agency suspends deductibles, copayments, coinsurance, and other cost sharing charges as follows:

2. ____ The agency suspends enrollment fees, premiums and similar charges for:

    a. _____ All beneficiaries

    b. _____ The following eligibility groups or categorical populations:

3. _____ The agency allows waiver of payment of the enrollment fee, premiums and similar charges for undue hardship.

Please specify the standard(s) and/or criteria that the state will use to determine undue hardship.

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Section D – Benefits

Benefits:

1. ___ The agency adds the following optional benefits in its state plan (include service descriptions, provider qualifications, and limitations on amount, duration or scope of the benefit):

2. ___ The agency makes the following adjustments to benefits currently covered in the state plan:

3. ___ The agency assures that newly added benefits or adjustments to benefits comply with all applicable statutory requirements, including the statewideness requirements found at 1902(a)(1), comparability requirements found at 1902(a)(10)(B), and free choice of provider requirements found at 1902(a)(23).

4. ___ Application to Alternative Benefit Plans (ABP). The state adheres to all ABP provisions in 42 CFR Part 440, Subpart C. This section only applies to states that have an approved ABP(s).

    a. ___ The agency assures that these newly added and/or adjusted benefits will be made available to individuals receiving services under ABPs.

    b. ____ Individuals receiving services under ABPs will not receive these newly added and/or adjusted benefits, or will only receive the following subset:

Telehealth:

5. ___ The agency utilizes telehealth in the following manner, which may be different than outlined in the state's approved state plan:

Drug Benefit:

6. _____ The agency makes the following adjustments to the day supply or quantity limit for covered outpatient drugs. The agency should only make this modification if its current state plan pages have limits on the amount of medication dispensed.

This SPA is in addition to Louisiana's approved Medicaid Disaster Relief SPAs and does not supersede any provisions in those SPAs.

7. ____ Prior authorization for medications is expanded by automatic renewal without clinical review, or time/quantity extensions.

8. ____ The agency makes the following payment adjustment to the professional dispensing fee when additional costs are incurred by the providers for delivery. States will need to supply documentation to justify the additional fees.

9. ___ The agency makes exceptions to their published Preferred Drug List if drug shortages occur. This would include options for covering a brand name drug product that is a multi-source drug if a generic drug option is not available.

Section E – Payments

Optional benefits described in Section D:

1. _____ Newly added benefits described in Section D are paid using the following methodology:

   a. ____ Published fee schedules –

      Effective date (enter date of change): _____

      Location (list published location): _____

   b. ____ Other:

Describe methodology here.

Increases to state plan payment methodologies:

2. X____The agency increases payment rates for the following services:

During the statewide COVID-19 public health emergency (PHE), Louisiana Medicaid will establish an alternative payment methodology (APM) for federally qualified health centers (FQHCs) and rural health clinics (RHCs) to receive reimbursement for COVID-19 monoclonal treatment-only visits at the Medicare rate. *Payments under this APM are to cover the additional costs associated with the COVID-19 monoclonal treatment by FQHCs and RHCs during COVID-19 monoclonal treatment visits as the PPS cost base for FQHCs and RHCs did not include these costs.*

This SPA is in addition to Louisiana's approved Medicaid Disaster Relief SPAs and does not supersede any provisions in those SPAs.

The payments for the monoclonal treatment-only visits provide a needed supplement to FQHCs and RHC reimbursement during this public health emergency.

The supplemental amounts made under this APM are in addition to the Prospective Payment System (PPS) rate paid to FQHCs and RHCs for an encounter.

The amount in total paid to FQHC and RHC providers is at least their provider-specific PPS rate.

Reimbursement will start with dates of services on September 1, 2021, and continue through the end of the federal PHE.

Payments made to the FQHCs and RHCs under this APM will be made per submitted claim for a COVID-19 monoclonal treatment-only visit, which will be reimbursed at the Medicare rate.

When the COVID-19 monoclonal treatment is administered as part of an otherwise billable FQHC/RHC encounter per Attachment 4.19-B, the encounter is reimbursed under the existing PPS/APM per Attachment 4.19-B; and, no separate reimbursement will be made.

FQHC and RHC providers must agree to receive the APM.

a. __X__ Payment increases are targeted based on the following criteria:

FQHC and RHC providers that administer the COVID-19 treatment when E&M service is not performed.

FQHC and RHC providers must agree to the APM to obtain reimbursement for the COVID 19 monoclonal treatment-only visits at the Medicare cost per COVID-19 treatment administration.

b. Payments are increased through:

i. ____ A supplemental payment or add-on within applicable upper payment limits:

ii. __X__ An increase to rates as described below.

_____ Uniformly by the following percentage:

__X__ Through a modification to published fee schedules –

Effective date (enter date of change): September 27, 2021

This SPA is in addition to Louisiana's approved Medicaid Disaster Relief SPAs and does not supersede any provisions in those SPAs.

Location (list published location): Louisiana Medicaid COVID-19 Fee Schedules

__X__ Up to the Medicare payments for equivalent services.

By the following factors:

Payment for services delivered via telehealth:

3. _____ For the duration of the emergency, the state authorizes payments for telehealth services that:

    a. ____ Are not otherwise paid under the Medicaid state plan;

    b. ____ Differ from payments for the same services when provided face to face;

    c. ____ Differ from current state plan provisions governing reimbursement for telehealth;

Describe telehealth payment variation.

    d. ____ Include payment for ancillary costs associated with the delivery of covered services via telehealth, (if applicable), as follows:

        i. ____ Ancillary cost associated with the originating site for telehealth is incorporated into fee-for-service rates.

        ii. ____ Ancillary cost associated with the originating site for telehealth is separately reimbursed as an administrative cost by the state when a Medicaid service is delivered.

Other:

4. _____Other payment changes:

Section F – Post-Eligibility Treatment of Income

1. ____ The state elects to modify the basic personal needs allowance for institutionalized individuals. The basic personal needs allowance is equal to one of the following amounts:

    a. ____ The individual's total income

    b. ____ 300 percent of the SSI federal benefit rate

This SPA is in addition to Louisiana's approved Medicaid Disaster Relief SPAs and does not supersede any provisions in those SPAs.

c. ____ Other reasonable amount: _____

2. ____ The state elects a new variance to the basic personal needs allowance. (Note: Election of this option is not dependent on a state electing the option described the option in F.1. above.)

The state protects amounts exceeding the basic personal needs allowance for individuals who have the following greater personal needs:

Please describe the group or groups of individuals with greater needs and the amount(s) protected for each group or groups.

Section G – Other Policies and Procedures Differing from Approved Medicaid State Plan /Additional Information

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1148 (Expires 03/31/2021). The time required to complete this information collection is estimated to average 1 to 2 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. Your response is required to receive a waiver under Section 1135 of the Social Security Act. All responses are public and will be made available on the CMS web site. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. ***CMS Disclosure*** Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact the Centers for Medicaid & CHIP Services at 410-786-3870.

This SPA is in addition to Louisiana's approved Medicaid Disaster Relief SPAs and does not supersede any provisions in those SPAs.

LA SPA TN 21-0025
Federally Qualified Health Centers and Rural Health Clinics
Alternative Payment Methodology for COVID-19 Monoclonal Treatment
Effective date: September 1, 2021

Medicaid Funding Questions

The following questions are being asked and should be answered in relation to all amended payments made to providers paid pursuant to a methodology described in Attachments 4.19-A, 4.19-B, and 4.-19-D of this SPA.

1. Section 1903(a)(1) provides that Federal matching funds are only available for expenditures made by States for services under the approved State plan. Do providers receive and retain the total Medicaid expenditures claimed by the State (includes normal per diem, supplemental, enhanced payments, other) or is any portion of the payments returned to the State, local governmental entity, or any other intermediary organization? If providers are required to return any portion of payments, please provide a full description of the repayment process. Include in your response a full description of the methodology for the return of any of the payments, a complete listing of providers that return a portion of their payments, the amount or percentage of payments that are returned and the disposition and use of the funds once they are returned to the State (i.e., general fund, medical services account, etc.)

   RESPONSE:
   Providers will receive and retain 100 percent of the payments. No portion of the payments is returned to the State.

2. Section 1902(a)(2) provides that the lack of adequate funds from local sources will not result in lowering the amount, duration, scope, or quality of care and services available under the plan. Please describe how the state share of each type of Medicaid payment (normal per diem, supplemental, enhanced, other) is funded. Please describe whether the state share is from appropriations from the legislature to the Medicaid agency, through intergovernmental transfer agreements (IGTs), certified public expenditures (CPEs), provider taxes, or any other mechanism used by the state to provide state share. Note that, if the appropriation is not to the Medicaid agency, the source of the state share would necessarily be derived through either through an IGT or CPE. In this case, please identify the agency to which the funds are appropriated. Please provide an estimate of total expenditure and State share amounts for each type of Medicaid payment. If any of the non- federal share is being provided using IGTs or CPEs, please fully describe the matching arrangement including when the state agency receives the transferred amounts from the local governmental entity transferring the funds. If CPEs are used, please describe the methodology used by the state to verify that the total expenditures being certified are eligible for Federal matching funds in accordance with 42 CFR 433.51(b). For any payment funded by CPEs or IGTs, please provide the following:
   (i) a complete list of the names of entities transferring or certifying funds;
   (ii) the operational nature of the entity (state, county, city, other);
   (iii) the total amounts transferred or certified by each entity;
   (iv) clarify whether the certifying or transferring entity has general taxing authority: and,
   (v) whether the certifying or transferring entity received appropriations

(identify level of appropriations).

RESPONSE:
The State share is paid from the state general fund, which is directly appropriated to the Medicaid agency.

3. Section 1902(a)(30) requires that payments for services be consistent with efficiency, economy, and quality of care. Section 1903(a)(1) provides for Federal financial participation to States for expenditures for services under an approved State plan. If supplemental or enhanced payments are made, please provide the total amount for each type of supplemental or enhanced payment made to each provider type.

RESPONSE:
This SPA does not involve supplemental or enhanced payments.

4. For clinic or outpatient hospital services please provide a detailed description of the methodology used by the state to estimate the upper payment limit (UPL) for each class of providers (State owned or operated, non-state government owned or operated, and privately owned or operated). Please provide a current (i.e., applicable to the current rate year) UPL demonstration.

RESPONSE:
Not applicable to this proposed SPA.

5. Does any governmental provider receive payments that in the aggregate (normal per diem, supplemental, enhanced, other) exceed their reasonable costs of providing services? If payments exceed the cost of services, do you recoup the excess and return the Federal share of the excess to CMS on the quarterly expenditure report?

RESPONSE:
The State does not have any public/governmental providers receiving payments that exceed their reasonable costs of services provided.