

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 854	Date: January 11, 2019
	Change Request 10901

Transmittal 829, dated October 3, 2018, is being rescinded and replaced by Transmittal 854, dated January 11, 2019, to update 3 business requirements (BR) and their related chapter 13 manual instructions. This correction will revise BRs 10901.7 and 10901.7.1, including the related section 13.2.4.3, to add language that indicates that MACs have the discretion to host multi-jurisdictional CACs ; revise BR 10901.24, including the related section 13.5.2.2, to strike the words “in their proposed LCD” and strike the words "meeting logistics" and replace with "attendance information"; and BR 10901.26, including the related section 13.5.3, to add language that allows MACs the option of providing a hyperlink to the FDA clearance to market. All other information remains the same.

SUBJECT: Local Coverage Determinations (LCDs)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to notify the Medicare Administrative Contractors (MACs) that, in accordance with section 4009 of H.R. 34-21st Century Cures Act (Public Law 114-255), this manual is being updated with detailed changes to the LCD process.

EFFECTIVE DATE: September 26, 2018

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: January 8, 2019 - unless otherwise specified.

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	Chapter 13/Table of Contents
R	13/13.1/Glossary of Acronyms
R	13/13.1/13.1.2/LCD Definition and Statutory Authority for LCDs
N	13/13.2/LCD Process
N	13/13.2/13.2.1/General LCD Process Overview
N	13/13.2/13.2.2/Requests
N	13/13.2/13.2.2.1/Informal Meetings
N	13/13.2/13.2.2.2/New LCD Requests
N	13/13.2/13.2.2.3/New LCD Request Requirements
N	13/13.2/13.2.4/Proposed LCD
N	13/13.2/13.2.4.1/Proposed Decision and Posting of LCD Summary Sheet
N	13/13.2/13.2.4.2/Public Comment
N	13/13.2/13.2.4.3/Contractor Advisory Committee (CAC)
N	13/13.2/13.2.4.4/Open Meeting
N	13/13.2/13.2.5/Final Determination
N	13/13.2/13.2.5.1/Response to Public Comment
N	13/13.2/13.2.6/Notice Period
R	13/13.3 /LCD Reconsideration Request
N	13/13.3/13.3.1/Web site Requirements for the LCD Reconsideration Process
N	13/13.3/13.3.2/Valid LCD Reconsideration Request Requirements
N	13/13.3/13.3.3/Process Requirements
R	13/13.4/Challenge of an LCD
R	13/13.5/LCD Content
R	13/13.5/13.5.1/General Requirements
R	13/13.5/13.5.2/Consultation
N	13/13.5/13.5.2.1/Consultation Summary
N	13/13.5/13.5.2.2/CAC Recommendations
R	13/13.5/13.5.3/Evidentiary Content
R	13/13.5/13.5.4/Reasonable and Necessary Provision in an LCD
N	13/13.5/13.5.5/Public Comment
N	13/13.5/13.5.6/Final Decision
R	13/13.6/LCD Record

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	Exhibits/Table of Contents
D	Exhibits/3/Description of CAC Members
D	Exhibits/3/3.1/Physicians
D	Exhibits/3/3.2/Clinical Laboratory Representative
D	Exhibits/3/3.3/Beneficiaries
D	Exhibits/3/3.4/Other Organizations
D	Exhibits/6/LMRP Format
D	Exhibits/6/6.1/Local Coverage Determination (LCD) Format

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

Attachment - Business Requirements

Pub. 100-08	Transmittal: 854	Date: January 11, 2019	Change Request: 10901
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SUBJECT: Local Coverage Determinations (LCDs)

EFFECTIVE DATE: September 26, 2018

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IMPLEMENTATION DATE: January 8, 2019 - unless otherwise specified.

I. GENERAL INFORMATION

A. Background: Stakeholders have provided the CMS with valuable insight regarding LCD process modernization through feedback received in the proposed calendar year 2018 Physician Fee Schedule Rule (82 FR 33950) and through various meetings and correspondence with providers and healthcare associations. Most stakeholders acknowledged that local coverage process is an important means to provide decisions on the items and services that benefit Medicare’s beneficiaries and ensure beneficiary access to life saving and medically necessary products and procedures. However, concerns have been raised related to the lack of local coverage process transparency including processes for notifying stakeholders of proposed revisions to, and drafting of, new LCDs. Additional stakeholder concerns include: ineffective MAC processes for soliciting and providing feedback to stakeholders on information provided during open public meetings, lack of non-physician representation on Contractor Advisory Committees (CACs), and concerns that CACs are closed meetings and are not open to the public.

The revisions (additions, deletions, corrections) to this manual reflect policy process changes in response to new statutory (21st century Cures Act) requirements and stakeholder comments. These changes will help to increase transparency, clarity, consistency, improve provider burden and public relations while retaining the ability to be responsive to local clinical and coverage policy concerns.

The 2016 21st Century Cures Act included changes to the LCD process, adding language to section 1862(l)(5)(D) of the Social Security Act (the Act) to describe the LCD process. Section 1862(l)(5)(D) of the Act requires each MAC that develops an LCD to make available on the Internet website of such contractor and on the Medicare Internet website, at least 45 days before the effective date of such determination, the following information:

1. Such determination in its entirety.
2. Where and when the proposed determination was first made public.
3. Hyperlinks to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.
4. A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence.
5. An explanation of the rationale that supports such determination.

We are revising our instructions to contractors in Pub. 100-08, Chapter 13 of the Medicare Program Integrity Manual in order to reflect these policy changes. 42 CFR §426 outlines all the requirements regarding the LCD Challenge process; therefore, we believe sections 13.13.1-13.13.15 in Chapter 13 of Pub. 100-08 are

duplicative and will be deleted.

B. Policy: The 2016 21st Century Cures Act and Section 1862(1)(5)(D) of the Act

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								Other
		A/B MAC			D ME M AC	Shared-System Maintainers				
		A	B	HH H		FI SS	M CS	V MS	C W F	
10901.1	MACs may allow for informal meetings with interested parties in the MAC's jurisdiction to discuss potential LCD requests.	X	X	X	X					
10901.1.1	MACs shall publish on their contractor website how an interested party can contact them to set up an informal meeting.	X	X	X	X					
10901.2	The New LCD Request Process is a mechanism by which interested parties within a contractor's jurisdiction can request a new LCD. Contractors shall consider all new LCD requests from: <ul style="list-style-type: none"> • Beneficiaries residing or receiving care in a contractor's jurisdiction; • Health care professionals doing business in a contractor's jurisdiction; and • Any interested party doing business in a contractor's jurisdiction. 	X	X	X	X					
10901.3	Contractors shall consider New LCD Requests to be a complete, formal request if the following are met: <ul style="list-style-type: none"> • The request is in writing and can be sent to the MAC via e-mail, facsimile or written letter; • The request clearly identifies the statutorily-defined Medicare benefit category to which the requestor believes the item or service falls under and provides a rationale justifying the assignment; • The request shall identify the language that the requestor wants in an LCD; 	X	X	X	X					

Number	Requirement	Responsibility								
		A/B MAC			D ME M AC	Shared-System Maintainers				Oth er
		A	B	HH H		FI SS	M CS	V MS	C W F	
	<ul style="list-style-type: none"> The request shall include a justification supported by peer-reviewed evidence. Full copies of published evidence to be considered shall be included and failure to include same invalidates the request; The request shall include information that addresses the relevance, usefulness, clinical health outcomes, or the medical benefits of the item or service; and The request shall include information that fully explains the design, purpose, and/or method, as appropriate, of using the item or service for which the request is made. 									
10901.3.1	The MAC will review materials received within 60 calendar days upon receipt and determine whether the request is complete or incomplete.	X	X	X	X					
10901.3.2	If the request is incomplete, the contractor shall respond, in writing, to the requestor explaining why the request was incomplete.	X	X	X	X					
10901.3.3	If the request is complete, the MAC shall follow the process outlined in section 13.2 in chapter 13 of Pub.100-08.	X	X	X	X					
10901.3.4	If the MAC requires an extension to the timeframes noted above, the MAC shall inform their COR and Business Function Lead (BFL) in writing. The MAC shall also provide their rationale for the extension request.	X	X	X	X					
10901.4	When a MAC consults with an expert, they shall inform and obtain consent from the expert that their opinion may be used and clearly identified within the proposed or final LCD.	X	X	X	X					
10901.5	For all proposed LCDs, with limited exceptions noted below, MACs shall follow the LCD process, consisting of consultation,	X	X	X	X					

Number	Requirement	Responsibility								
		A/B MAC			D ME M AC	Shared-System Maintainers				Oth er
		A	B	HH H		FI SS	M CS	V MS	C W F	
	<p>publication of proposed LCD, open meeting concerning the proposed policy, opportunity for public comment in writing, publication of a final LCD that includes a response to public comments received and notice to the public of new policy 45 days in advance of the effective date. These processes shall be used for all LCDs except in the following situations:</p> <ul style="list-style-type: none"> • Revised LCD Being Issued for Compelling Reasons • Revised LCD that Makes a Non-Substantive Correction - For example, typographical or grammatical errors that do not substantially change the LCD. • Revised LCD that Makes a Non-Discretionary Coverage Update - Contractors shall update LCDs to reflect changes in Statutes, Federal regulations, CMS Rulings, National Coverage Determinations (NCDs), HCPCS code changes for DME, coverage provisions in interpretive manuals, and payment policies • Revise LCD to effectuate an Administrative Law Judge's decision to nullify an existing LCD due to an LCD Challenge. 									
10901.5.1	Contractors shall obtain explicit approval from the CMS contracting officer and BFL in all other situations.	X	X	X	X					
10901.6	Once the proposed LCD is published, MACs shall provide a minimum of 45 calendar days for public comment.	X	X	X	X					
10901.6.1	MACs shall contact the CMS BFL if they determine an extension to the comment period is needed.	X	X	X	X					
10901.7	MACs shall establish one CAC per state or have the option of establishing one CAC per jurisdiction or multi-jurisdictional CAC with representation from each state.	X	X	X	X					

Number	Requirement	Responsibility								
		A/B MAC			D M E M A C	Shared-System Maintainers				Oth er
		A	B	HH H		FI SS	M CS	V MS	C W F	
10901.7.1	It is expected that if a MAC chooses to have one CAC per jurisdiction or multi-jurisdictional CAC, the MAC shall endeavor to ensure that each state has a full committee and the opportunity to discuss the quality of the evidence used to make a determination.	X	X	X	X					
10901.7.2	The MAC shall endeavor to ensure each specialty that serves on the CAC shall have only at least one member and a designated alternate approved by the MAC.	X	X	X						
10901.7.3	MACs shall work with CAC members to select a meeting location that will optimize participation. Contractors have the option of hosting in-person or telephonic/video/on-line conference/etc. meetings.	X	X	X	X					
10901.7.4	MACs shall ensure all CAC meetings will be open to the public to attend and observe.	X	X	X	X					
10901.7.5	MACs shall keep a copy of the number of CAC attendees and make a copy available to CMS BFL and COR upon request.	X	X	X	X					
10901.7.6	MACs shall record (video, audio or both) the CAC meetings and as part of the LCD record, assure the recording is maintained on their contractor website.	X	X	X	X					
10901.7.7	Participation in the CAC is considered voluntary. MACs shall not provide an honorarium or other forms of compensation to members.	X	X	X	X					
10901.8	After the proposed LCD is made public, MACs shall hold open meetings to discuss the review of the evidence and the rationale for the proposed LCD(s) with stakeholders in their jurisdiction.	X	X	X	X					
10901.8.1	MACs should endeavor to accommodate some in-person attendance, subject to limitations based on venue.	X	X	X	X					
10901.8.2	Contractors shall remain sensitive to parties that may have an interest in an issue and endeavor to invite them to participate in meetings at which a related LCD is being	X	X	X	X					

Number	Requirement	Responsibility								Other
		A/B MAC			D ME M AC	Shared-System Maintainers				
		A	B	HH H		FI SS	M CS	V MS	C W F	
	discussed.									
10901.8.2.1	MACs shall provide an email address on their contractor website where all interested parties shall submit their presentation materials.	X	X	X	X					
10901.8.3	In recognition that the efficient use of resources may require several proposed LCDs to be discussed during one meeting, time for presentation by interested parties may be limited. MACs shall ensure the presentation time shall be equally divided amongst the LCDs discussed at the meeting.	X	X	X	X					
10901.8.4	MACs shall keep a copy of the number of attendees and make a copy available to CMS BFL and COR upon request.	X	X	X	X					
10901.8.5	MACs shall record (video, audio or both) the Open Meetings and as part of the LCD record, assure the recording is maintained on their contractor website.	X	X	X	X					
10901.8.6	MACs shall notify the public about the dates, times, and location for the open meeting. MACs have the option of setting up email listservs to announce this information or may use other education methods to adequately inform the public.	X	X	X	X					
10901.8.6.1	The MACs shall ensure that the listserv or other method clearly identifies the location, times, dates and telephone/video/on-line conference information for the open meeting to ensure that this information is clearly distinguished from the information for the CAC meetings.	X	X	X	X					
10901.8.7	MACs shall post the planned agenda for the open meeting a minimum of two weeks prior to the event on their contractor website and shall inform the public that the agenda has been posted.	X	X	X	X					
10901.9	After the close of the comment period and the required meetings and consultation, the MACs shall publish the final LCD and the Response to Comment (RTC) Article on the	X	X	X	X					

Number	Requirement	Responsibility								
		A/B MAC			D M E M A C	Shared-System Maintainers				Oth er
		A	B	HH H		FI SS	M CS	V MS	C W F	
	Medicare Coverage Database (MCD).									
10901.9.1	MACs shall respond to all comments received during the comment period of the proposed LCD by using the RTC article associated with the LCD. The RTC Article is published on the start date of the notice period. The RTC Article will remain publically available indefinitely on the MCD or the MCD Archive.	X	X	X	X					
10901.10	The MACs shall publish the final LCD on the MCD. The date the LCD is published on the MCD marks the beginning of the required notice period of a minimum 45 calendar days before the LCD can take effect.	X	X	X	X					
10901.10.1	If the MAC would like to extend the notice period, they shall seek approval from CMS BFL. If the notice period is not extended by the contractor, the effective date of the LCD is the 46th calendar day after the notice period began	X	X	X	X					
10901.11	MACs shall add to their MAC Web sites information on the LCD Reconsideration Process.	X	X	X	X					
10901.11.1	The MACs shall ensure that this information is listed on the LCD home page of the MAC's Web site. It shall be labeled "LCD Reconsideration Process" and shall include: • A description of the LCD Reconsideration Process; and • Instructions for submitting LCD reconsideration requests, including postal, e-mail, and fax addresses where requests may be submitted.	X	X	X	X					
10901.12	MACs shall consider all LCD reconsideration requests from:	X	X	X	X					

Number	Requirement	Responsibility								
		A/B MAC			D M E M A C	Shared-System Maintainers				Oth er
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	<ul style="list-style-type: none"> • Beneficiaries residing or receiving care in a contractor's jurisdiction; and • Providers doing business in a contractor's jurisdiction • Any interested party doing business in a contractor's jurisdiction 									
10901.1 3	<p>MACs should only accept reconsideration requests for LCDs published as an effective final. Requests shall not be accepted for other documents including:</p> <ul style="list-style-type: none"> • NCDs; • Coverage provisions in interpretive manuals; • Proposed LCDs; • Template LCDs, unless or until they are adopted and in effect by the contractor; • Retired LCDs; • Individual claim determinations • Bulletins, articles, training materials; and • Any instance in which no LCD exists, i.e., requests for development of an LCD 	X	X	X	X					
10901.1 4	<p>If modification of the LCD would conflict with an NCD, the request would not be valid. The MAC should refer the requestor to the NCD reconsideration process. Requestors can be referred to http://www.cms.gov/DeterminationProcess/01_overview.asp#regs.</p>	X	X	X	X					
10901.1 5	<p>Any request for LCD reconsideration that, after MAC review, is determined to not meet these criteria is invalid. MACs shall have the discretion to consolidate valid requests, if similar requests are received.</p>	X	X	X	X					
10901.1 5.1	<p>Within 60 calendar days of the day the request is received, the MAC shall determine</p>	X	X	X	X					

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		A/B MAC			D M E M A C	Shared-System Maintainers				Oth er
		A	B	HH H		FI SS	M CS	V MS	C W F	
	whether the request is valid or invalid.									
10901.1 5.1.1	If the request is invalid, the MAC shall respond in writing, to the requestor explaining why the request was invalid.	X	X	X	X					
10901.1 5.2	If the request is valid, the contractor shall follow the requirements below. The MAC shall open the LCD and follow the LCD process as outlined in section 13.2 of this manual or include the LCD on the MAC's waiting list.	X	X	X	X					
10901.1 5.3	The MAC shall respond, in writing, to the requestor notifying the requestor of the acceptance, and if applicable, wait-listing, of the reconsideration request.	X	X	X	X					
10901.1 5.4	Contractors shall keep an internal list of the LCD Reconsideration Requests received and the dates, subject, and disposition of each one.	X	X	X	X					
10901.1 6	Contractors shall follow all LCD Challenge requirements outlined in 42 CFR part 426.	X	X	X	X					
10901.1 7	The MACs shall publish all proposed and final LCDs and LCD related articles on the MCD. The public may access the MCD at http://www.cms.gov/medicare-coverage-database . <ul style="list-style-type: none"> MACs shall ensure the accuracy of the information entered into the MCD. If a MAC decides to have LCDs and related articles on their MAC web sites, then the MAC shall link from their MAC website to the MCD. 	X	X	X	X					
10901.1 8	MACs shall finalize or retire all proposed LCDs within a rolling year of publication date of the proposed LCD on the MCD (365 days). If an unusual circumstance occurs and the MAC wishes to request an exception to this requirement, they shall notify their COR and LCD BFLs at least 21 business days	X	X	X	X					

Number	Requirement	Responsibility								
		A/B MAC			D ME M AC	Shared-System Maintainers				Oth er
		A	B	HH H		FI SS	M CS	V MS	C W F	
	before the one year expiration date.									
10901.1 9	The MAC shall ensure that all LCDs do not conflict with all statutes, rulings, regulations, and national coverage, payment, and coding policies.	X	X	X	X					
10901.2 0	For all new and revised LCDs, MACs shall no longer include national policy language found in statute, regulations, rulings, interpretive manual instructions, etc. in the coverage and indications section of their LCDs. If contractors need to reference a national policy in the coverage and indications section of their LCD, they shall cite the reference (e.g., publication number, Medicare title of manual, section of manual).	X	X	X	X					
10901.2 1	MACs shall remove all codes from LCDs and place them in billing & coding articles that are linked to the LCD. CMS will provide additional instructions on the date upon which this change will be effective.	X	X	X	X					
10901.2 2	The MAC shall summarize the opinions received as a result of consultation with healthcare professional expert(s), professional societies, etc. prior to the drafting of a proposed LCD, and include this information in the proposed LCD.	X	X	X	X					
10901.2 3	When a MAC determines that a CAC consultation should be sought for a proposed LCD, the MAC shall include the summary of recommendations from the CAC regarding the policy in the Final LCD.	X	X	X	X					
10901.2 4	Contractors shall clearly identify attendance information consisting of location, time and date for the CAC meeting(s) and ensure that these are clearly distinguished from the information for the Open meeting(s), even if they occur on the same day at the same location.	X	X	X	X					
10901.2 4.1	The MAC shall also make available a means to accommodate reasonable requests for assistance from stakeholders who are hearing	X	X	X	X					

Number	Requirement	Responsibility								
		A/B MAC			D ME M AC	Shared-System Maintainers				Oth er
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	or visually impaired.									
10901.2 4.2	The MAC shall have the discretion to determine the frequency of the CAC meetings and shall base the meetings on the appropriateness and on the volume of LCDs that require CAC consultation as part of the LCD process.	X	X	X						
10901.2 5	In every proposed and final LCD, the MAC shall summarize the evidence that supports coverage, limited coverage, maintenance of existing coverage in cases of LCD reconsideration or non-coverage. At a minimum, the summary should include the following: <ul style="list-style-type: none"> • a complete description of the item or service under review; • a narrative that describes the scientific evidence supporting the clinical indications for the item or service; • the target Medicare population; and • whether the item or service is intended for use by health care providers or beneficiaries. 	X	X	X	X					
10901.2 6	If the item or service is regulated by the Food and Drug Administration (FDA), and determined by the MAC to be reasonable and necessary, information regarding the use of the item or service subject to the FDA labeling requirements shall be included. MACs have the option of providing a hyperlink to the FDA clearance to market to meet this requirement.	X	X	X						
10901.2 7	In conducting a review, MACs shall use the available evidence, such as published original research, systematic reviews and meta-analyses, and evidence-based consensus statements and guidelines. Proprietary information, submitted by the requestor, not available to the public shall not be considered. The review shall include a summary of all the evidence used to support the determination and may be grouped by	X	X	X	X					

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		A/B MAC			D ME M AC	Shared-System Maintainers				Oth er
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	type of evidence evaluated.									
10901.2 8	MACs shall list all articles and sources that led to the LCD in the Bibliography. The citations shall be consistent with the American Medical Association Manual of Style.	X	X	X	X					
10901.2 9	MACs shall explain the rationale that supports their coverage determination of covered, non-covered, or limited coverage. The rationale is the reasoning leading to the coverage determination.	X	X	X	X					
10901.3 0	If it is appropriate for a MAC to provide coding/billing information to help implement the coverage policy, the MAC shall publish the coding/billing article at the same time they publish the proposed LCD.	X	X	X	X					
10901.3 1	Contractors shall determine and describe in the LCD the circumstances under which the item or service is reasonable and necessary under section 1862(a)(1)(A) of the Act. Contractors shall determine if evidence exists to consider an item or service to be reasonable and necessary if the contractor determines that the service is: <ul style="list-style-type: none"> • Safe and effective; • Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and • Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is: <ul style="list-style-type: none"> o Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member; 	X	X	X	X					

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		A/B MAC			D ME M AC	Shared-System Maintainers				Oth er
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	<ul style="list-style-type: none"> o Furnished in a setting appropriate to the patient's medical needs and condition; o Ordered and furnished by qualified personnel; o One that meets, but does not exceed, the patient's medical need; and o At least as beneficial as an existing and available medically appropriate alternative 									
10901.3 2	MACs shall provide a minimum of 45 calendar days for public comment on all proposed LCDs.	X	X	X	X					
10901.3 2.1	MACs shall respond to all timely received public comments, and may group similar comments and responses in logical categories in the RTC article.	X	X	X	X					
10901.3 3	After the close of the comment period and the required meetings, the MACs shall publish a final LCD to the MCD.	X	X	X	X					
10901.3 3.1	MACs shall link from their contractor website to the final LCD on the MCD.	X	X	X	X					
10901.3 3.2	The MAC shall respond to all comments received, via the RTC article which shall be published on the MCD at the same time as the publication of the final LCD. MACs shall ensure the final LCD and RTC article are related on the MCD.	X	X	X	X					
10901.3 3.3	MACs shall notify the public that a final decision has been published and provide the Web link to the final decision. MACs shall use several tools at their disposal to educate providers, including the "What's New Report" on the MCD, setting up email listservs, or other 508 compliant and accessible means to adequately inform stakeholders.	X	X	X	X					
10901.3 3.4	MACs shall notify the public that a final determination has been published and provide the Web link to the final decision. MACs may use several tools at their disposal	X	X	X	X					

Number	Requirement	Responsibility								
		A/B MAC			D M E M A C	Shared-System Maintainers				Oth er
		A	B	HH H		FI SS	M CS	V MS	C W F	
	to notify the public, including the "What's New Report" on the MCD, setting up listservs, or other 508 compliant and accessible means to inform stakeholders.									
10901.34	The contractors shall maintain the LCD record for a minimum of 6 years and 3 months from the date the LCD is retired.	X	X	X	X					
10901.34.1	Contractors shall have a mechanism for archiving retired LCDs. This mechanism shall also allow the contractor to respond to requests and retrieve the LCD record.	X	X	X	X					
10901.35	After 6 years and 3 months from the date the LCD is retired, the contractors shall destroy the LCD record. However, contractors shall not destroy the LCD record if it relates to a current investigation of litigation/negotiation; ongoing Workers' Compensation set aside arrangements; or documents which prompt suspicions of fraud and abuse of items or services.	X	X	X	X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
10901.36	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release	X	X	X	X	

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	notifications, or review them in the MLN Connects weekly newsletter.					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage) , Karen Reinhardt, 410-786-0189 or karen.reinhardt@cms.hhs.gov , Marie Casey, 410-786-7861 or marie.casey@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare Program Integrity Manual

Chapter 13 – Local Coverage Determinations (*LCDs*)

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13.1 - Glossary of Acronyms

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

ALJ: Administrative Law Judge

BFL: Business Function Lead

BIPA: Benefits Improvement and Protection Act

CAC: Contractor Advisory Committee

CFR: Code of Federal Regulation

COR: Contracting Officer Representative

CMS: Centers for Medicare & Medicaid Services

DAB: Department of Appeals Board

FR: Federal Register

LCD: Local Coverage Determination

LCBE: Local Coverage Backend Database

MAC: Medicare Administrative Contractor

MCD: Medicare Coverage Database

PFS: Physician Fee Schedule

RTC: Response to Comments

SSA: Social Security Act

13.1.2 - Local Coverage Determinations (LCD) Definition & Statutory Authority for LCDs

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

An LCD, as defined in §1869(f)(2)(B) of the Social Security Act (SSA), is a determination by a Medicare Administrative Contractor (MAC) respecting whether or not a particular item or service is covered on a contractor-wide basis in accordance with section 1862(a)(1)(A) of the Act.

1869(f)(2)(A) of the SSA outlines the process for Administrative Law Judge (ALJ) and Department of Appeals Board (DAB) review of LCDs. This process is known as the LCD Challenge Process. Procedures related to this challenge process are described in 42 Code of Federal Regulation (CFR) part426.

§1862(l)(5)(B) of the SSA requires the MACs providing services within the same jurisdiction to consult on all new local coverage determinations within the jurisdiction.

The 2016 21st Century Cures Act included changes to the LCD process, adding language to 1862(l)(5)(D) of the SSA to describe the LCD process. Section 1862(l)(5)(D), of the SSA requires each MAC that develops an LCD to make available on the Internet website of such contractor and on the Medicare Internet website, at least 45 days before the effective date of such determination, the following information:

- (i) Such determination in its entirety.*

- (ii) *Where and when the proposed determination was first made public.*
- (iii) *Hyperlinks to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.*
- (iv) *A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence.*
- (v) *An explanation of the rationale that supports such determination.*

13.2 - LCD Process

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

13.2.1 - General LCD Process Overview

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

This section outlines the processes used for informal meetings prior to the development of an LCD, external requests to develop an LCD, consultations, the proposed determination, public comment, the Contractor Advisory Committee, final determination, and the notice period.

13.2.2 - Requests

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

13.2.2.1 - Informal Meetings

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

The LCD process may begin with informal meetings in which interested parties in the MAC's jurisdiction can informally discuss potential LCD requests. These meetings are for educational purposes only and are not pre-decisional negotiations. MACs should publish on their contractor websites how an interested party can contact them to set up an informal meeting. These meetings are permitted but are not required and the process allows requestors to communicate via conference call or in-person meeting before submitting a formal request. These meetings will assure that all relevant evidence needed for review for coverage is submitted with the request for a formal review.

13.2.2.2 - New LCD Requests

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

The New LCD Request Process is a mechanism by which interested parties within a contractor's jurisdiction can request a new LCD. Contractors consider all new LCD requests from:

- *Beneficiaries residing or receiving care in a contractor's jurisdiction;*
- *Health care professionals doing business in a contractor's jurisdiction; and*
- *Any interested party doing business in a contractor's jurisdiction.*

13.2.2.3 - New LCD Request Requirements

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

Contractors shall consider New LCD Requests to be a complete, formal request if the following are met:

- *The request is in writing and can be sent to the MAC via e-mail, facsimile or written letter;*
- *The request clearly identifies the statutorily-defined Medicare benefit category to which the requestor believes the item or service falls under and provides a rationale justifying the assignment;*
- *The request shall identify the language that the requestor wants in an LCD;*
- *The request shall include a justification supported by peer-reviewed evidence. Full copies of published evidence to be considered shall be included and failure to include same invalidates the request;*
- *The request shall include information that addresses the relevance, usefulness, clinical health outcomes, or the medical benefits of the item or service; and*
- *The request shall include information that fully explains the design, purpose, and/or method, as appropriate, of using the item or service for which the request is made.*

The MAC will review materials received within 60 calendar days upon receipt and determine whether the request is complete or incomplete. If the request is incomplete, the contractor shall respond, in writing, to the requestor explaining why the request was incomplete. If the request is complete, the MAC shall follow the process outlined in chapter 13 of Pub.100-08. A valid request response does not convey that a determination has been made whether or not the item or service will be covered or non-covered under 1862 (a)(1)(A) of the Act. The response to the requestor that the request is valid is simply an acknowledgement by the MAC of the receipt of a complete, valid request.

If the MAC requires an extension to the timeframes noted above, the MAC shall inform their COR and BFL in writing. The MAC shall also provide their rationale for the extension request.

13.2.3 - Clinical Guidelines, Consensus Documents and Consultation (Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

Prior to drafting and during the development of an LCD, if available the MACs shall supplement their research (see section 13.5.3) with clinical guidelines, consensus documents or consultation by experts (recognized authorities in the field), medical associations or other health care professionals for an advisory opinion, when applicable. When a MAC consults with an expert, they shall inform and obtain consent from the expert that their opinion may be used, disclosed publicly, and clearly identified as such within the proposed or final LCD. Acceptance by individual health care providers, or even a limited group of health care providers, does not indicate general acceptance of the item or service by the medical community.

13.2.4 - Proposed LCD (Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

All proposed LCDs, with limited exceptions noted below, must follow the LCD process outlined in 13.2 of this manual, consisting of consultation, publication of proposed LCD, open meeting concerning the proposed policy, opportunity for public comment in writing, publication of a final LCD that includes a response to public comments received and notice to public of new policy 45 days in advance of the effective date. These processes shall be used for all LCDs except in the following situations:

- *Revised LCD Being Issued for Compelling Reasons -*
- *Revised LCD that Makes a Non-Substantive Correction - For example, typographical or grammatical errors that do not substantially change the LCD.*
- *Revised LCD that Makes a Non-Discretionary Coverage Update - Contractors shall update LCDs to reflect changes in Statutes, Federal regulations, CMS Rulings, NCDs, HCPCS code changes for DME, coverage provisions in interpretive manuals, and payment policies.*

- *Revise LCD to effectuate an Administrative Law Judge's decision to nullify an existing LCD due to an LCD Challenge.*

Contractors must obtain explicit approval from the CMS Contracting Officer Representative (COR) and Business Function Lead (BFL) in all other situations (e.g. there is compelling new evidence that a procedure/device is highly unsafe and coverage must be removed immediately).

13.2.4.1 - Proposed Determination & Posting of LCD Summary Sheet

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

The Proposed LCD is the MACs proposed determination regarding coverage, non-coverage or limited coverage for a particular item or service. The public announcement of the MAC's proposed determination begins with the date the proposed LCD is published on the Medicare Coverage Database (MCD).

The LCD Summary Sheet is a document that summarizes contractor actions related to the LCD and includes open meeting and CAC information, if applicable. The LCD Summary Sheet will be posted to the MCD.

13.2.4.2 - Public Comment

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

Once the proposed LCD is published MACs shall provide a minimum of 45 calendar days for public comment. MACs shall contact CMS Business Function Lead (BFL) if they determine an extension to the comment period is needed.

13.2.4.3 – Contractor Advisory Committee (CAC)

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

MACs shall establish one CAC per state or have the option of establishing one CAC per jurisdiction or multi-jurisdictional CAC with representation from each state. It is expected that if a MAC chooses to have one CAC per jurisdiction or multi-jurisdictional CAC, the MAC shall endeavor to ensure that each state has a full committee and the opportunity to discuss the quality of evidence used to make a determination.

The purpose of the CAC is to provide a formal mechanism for healthcare professionals to be informed of the evidence used in developing the LCD and promote communications between the MAC and the healthcare community. CAC members should serve in an advisory capacity as representatives of their constituency to review the quality of the evidence used in the development of an LCD. The CAC is advisory in nature, with the final decision on all issues resting with MACs. Accordingly, the advice rendered by the CAC is most useful when it results from a process of full scientific inquiry and thoughtful discussion with careful framing of recommendations and clear identification of the basis of those recommendations.

The CAC is to be composed of healthcare professionals, beneficiary representatives, and representatives of medical organizations. The CAC is used to supplement the MAC's internal expertise and to ensure an unbiased and contemporary consideration of "state of the art" technology and science. CAC members are valued for their background, education, experience and/or expertise in a wide variety of scientific, clinical, and other related fields. The MAC shall endeavor to ensure each specialty that serves on the CAC shall have at least one member and a designated alternate approved by the MAC. If the CAC member or alternate cannot attend the CAC meeting, a substitute may attend if the MAC is notified and approved at least 1 week prior to the meeting. MACs shall work with CAC members to select a meeting location that will optimize participation. MACs shall keep a copy of the number of CAC attendees and make a copy available to CMS BFL and COR upon request. MACs shall record (video, audio or both) the CAC meetings and as part of the LCD record, assure the recording is maintained on their contractor website. Contractors have the option of hosting in-person and/or telephonic/video/on-line conference/etc. meetings. All CAC meetings will be open to the public to attend and observe Portions of the meeting not discussing evidence for

a proposed LCD, such as provider practice trend reporting or discussions related to fraud and abuse, may be closed to the public.

Participation in the CAC is considered voluntary. MACs do not provide an honorarium or other forms of compensation to members. Expenses are the responsibility of the individuals or the associations they represent.

13.2.4.4 - Open Meeting

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

After the proposed LCD is made public, MACs shall hold open meetings to discuss the review of the evidence and the rationale for the proposed LCD(s) with stakeholders in their jurisdiction. The open meeting should endeavor to accommodate some in-person attendance, subject to limitations based on venue. Interested parties (generally those that would be affected by the LCD, including providers, physicians, vendors, manufacturers, beneficiaries, caregivers, etc.) can make presentations of information related to the proposed LCDs. MACs should provide an email address on their contractor website where all interested parties shall submit their presentation materials. However, all formal comments must be submitted in writing to the MAC. Contractors shall remain sensitive to parties that may have an interest in an issue and endeavor to invite them to participate in meetings at which a related LCD is being discussed. In recognition that the efficient use of resources may require several proposed LCDs to be discussed during one meeting, time for presentation by interested parties may be limited. The presentation time shall be equally divided amongst the LCDs discussed at the meeting. Members of the CAC may also attend these open meetings. MACs shall keep a copy of the number of attendees and make a copy available to CMS BFL and COR upon request. MACs shall record (video, audio or both) the Open Meetings and as part of the LCD record, assure the recording is maintained on their contractor website.

MACs are required to notify the public about the dates, times, and location for the open meeting. MACs have the option of setting up email listservs to announce this information or may use other education methods to inform the public. The listserv or other method should clearly identify the location, times, dates and telephone/video/on-line conference information for the open meeting to ensure that this information is clearly distinguished from the information for the CAC meetings. MACs shall post the planned agenda for the open meeting a minimum of two weeks prior to the event on their contractor website and will inform the public that the agenda has been posted.

13.2.5 - Final Determination

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

After the close of the comment period and the required meetings and consultation, the final LCD and the Response to Comment (RTC) Article shall be published on the MCD.

A. Response to Public Comments

MACs respond to all comments received during the comment period of the proposed LCD by using the Response to Comment (RTC) article associated with the LCD. The RTC Article is published on the start date of the notice period. The RTC Article will remain publicly available indefinitely on the MCD or the MCD Archive.

13.2.6 - Notice Period

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

The date the final LCD is published on the MCD, marks the beginning of the required notice period of a minimum 45 calendar days before the LCD can take effect. If the MAC would like to extend the notice period, they shall seek approval from CMS BFL. If the notice period is not extended by the contractor, the effective date of the LCD is the 46th calendar day after the notice period began.

13.3 - LCD Reconsideration Process

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

The LCD reconsideration process is a mechanism by which a beneficiary or stakeholder (including a medical professional society or physician) in the MAC's jurisdiction can request a revision to an LCD. The LCD reconsideration process differs from an initial request for an LCD in that it is available only for final effective LCDs. The whole LCD or any provision of the LCD may be reconsidered. In addition, MACs have the discretion to revise or retire their LCDs at any time on their own initiative.

13.3.1 - Web site Requirements for the LCD Reconsideration Process

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

MACs shall add to their MAC Web sites information on the LCD Reconsideration Process. This information should be on the LCD home page of the MAC's Web site. It shall be labeled "LCD Reconsideration Process" and shall include:

- A description of the LCD Reconsideration Process; and*
- Instructions for submitting LCD reconsideration requests, including postal, e-mail, and fax addresses where requests may be submitted.*

13.3.2 - Valid LCD Reconsideration Request Requirements

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

MACs shall consider all LCD reconsideration requests from:

- Beneficiaries residing or receiving care in a contractor's jurisdiction; and*
- Providers doing business in a contractor's jurisdiction.*
- Any interested party doing business in a contractor's jurisdiction.*

*MACs should only accept reconsideration requests for LCDs published as an effective final. Requests shall **not** be accepted for other documents including:*

- National Coverage Determinations (NCDs);*
- Coverage provisions in interpretive manuals;*
- Proposed LCDs;*
- Template LCDs, unless or until they are adopted and in effect by the contractor;*
- Retired LCDs;*
- Individual claim determinations*
- Bulletins, articles, training materials; and*
- Any instance in which no LCD exists, i.e., requests for development of an LCD.*

If modification of the LCD would conflict with an NCD, the request would not be valid. The MAC should refer the requestor to the NCD reconsideration process. Requestors can be referred to http://www.cms.gov/DeterminationProcess/01_overview.asp#regs.

Requests shall be submitted in writing and shall identify the language that the requestor wants added to or deleted from an LCD. Requests shall include a justification supported by new evidence, which may materially affect the LCD's content or basis. Copies of published evidence shall be included. Any request for LCD reconsideration that, after MAC review, is determined to not meet these criteria is invalid. MACs have the discretion to consolidate valid requests if similar requests are received.

13.3.3 - Process Requirements

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

The requestor shall submit a valid LCD reconsideration request to the appropriate MAC, following instructions on the MAC's Web site.

Within 60 calendar days of the day the request is received, the MAC shall determine whether the request is valid or invalid. If the request is invalid, the contractor shall respond, in writing, to the requestor explaining why the request was invalid. If the request is valid, the contractor shall follow the requirements below.

The MAC shall open the LCD and follow the LCD process as outlined in section 13.2 of this manual or include the LCD on the MAC's waiting list. The MAC shall respond, in writing, to the requestor notifying the requestor of the acceptance, and if applicable, wait-listing, of the reconsideration request.

Contractors shall keep an internal list of the LCD Reconsideration Requests received and the dates, subject, and disposition of each one.

13.4 - Challenge of an LCD

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

In addition to creating the term "Local Coverage Determination" (LCD), section 1869(f) of the Social Security Act creates an appeals process for an "aggrieved party" to challenge LCDs/LCD provisions that are in effect at the time of the challenge. "Aggrieved party" is defined in regulation as a Medicare beneficiary, or the estate of a Medicare beneficiary, who is entitled to benefits under Part A, enrolled under Part B, or both (including an individual enrolled in fee-for-service Medicare, in a Medicare Advantage plan (MA), or in another Medicare managed care plan), and is in need of coverage for an item or service that would be denied by an LCD, as documented by the beneficiary's treating physician, regardless of whether the service has been received. An aggrieved party has obtained documentation of the need by the beneficiary's treating physician.

Contractors shall follow all LCD Challenge requirements outlined in 42 CFR part 426. As indicated in 42 CFR § 426.415 if appropriate, CMS may choose to participate as a party in the LCD Challenge process.

13.5 – LCD Content

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

13.5.1 - General Requirements

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

The Medicare Coverage Database (MCD) is the central repository that houses proposed, and final LCDs, and LCD related articles.

- *The MACs shall publish all proposed and final LCDs and LCD related articles on the MCD. The public may access the MCD at <http://www.cms.gov/medicare-coverage-database>.*
- *MACs must ensure the accuracy of the information entered into the MCD.*
- *If a MAC decides to have LCDs and related articles on their MAC web sites, then the MAC must link from their MAC website to the MCD.*

MACs shall finalize or retire all proposed LCDs within a rolling year of publication date of the proposed LCD on the MCD (365 days). If an unusual circumstance occurs and the MAC wishes to request an exception to this requirement, they shall notify their COR and LCD BFLs at least 21 business days before the one year expiration date.

The MAC shall ensure that all LCDs do not conflict with all statutes, rulings, regulations, and national coverage, payment, and coding policies.

For all new and revised LCDs MACs shall no longer include national policy language found in statute, regulations, rulings, interpretive manual instructions, etc. in the coverage and indications section of their LCDs. If contractors need to reference a national policy in the coverage and indications section of their LCD, they shall cite the reference (e.g. publication number, Medicare title of manual, section of manual) without reiterating the text from the policy.

It is no longer appropriate to include Current Procedure Terminology (CPT) codes or International Classification of Diseases-Tenth Revision-Clinical Modification (ICD-10-CM) codes in the LCDs. All CPT and ICD-10-CM codes shall be removed from LCDs and placed in billing & coding articles or Policy Articles that are to be published to the MCD and related to the LCD. CMS will provide additional instructions on the date upon which this change will be effective.

13.5.2 - Consultation

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

13.5.2.1 - Consultation Summary

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

The MAC shall summarize the opinions received as a result of consultation with healthcare professional expert(s), professional societies, etc. prior to the drafting of a proposed LCD, and include this information in the proposed LCD.

13.5.2.2 - CAC Recommendations

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

When a MAC determines that a CAC consultation should be sought for a proposed LCD, the summary of recommendations from the CAC regarding the policy shall be included in the Final LCD.

Contractors shall clearly identify, attendance information consisting of location, time and, date for the CAC meeting(s) and ensure that these are clearly distinguished from the information for the Open meeting(s) even if they occur on the same day at the same location. The MAC shall also make available a means to accommodate reasonable requests for assistance from stakeholders who are hearing or visually impaired. The frequency of the CAC meetings are at the discretion of the MAC and will be based on the appropriateness and on the volume of LCDs that require CAC consultation as part of the LCD process.

13.5.3 - Evidentiary Content

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

In every proposed and final LCD, the MAC must summarize the evidence that supports coverage, limited coverage, maintenance of existing coverage in cases of LCD reconsideration or non-coverage. At a minimum, the summary should include the following:

- a complete description of the item or service under review;*
- a narrative that describes the scientific evidence supporting the clinical indications for the item or service;*
- the target Medicare population; and*

- *whether the item or service is intended for use by health care providers or beneficiaries.*

If the item or service is regulated by the FDA, and determined by the MAC to be reasonable and necessary, information regarding the use of the item or service subject to the FDA indication, as applicable, shall be included. MACs have the option of providing a hyperlink to the FDA clearance to market to meet this requirement.

In conducting a review, MACs shall use the available evidence of general acceptance by the medical community, such as published original research in peer-reviewed medical journals, systematic reviews and meta-analyses, evidence-based consensus statements and clinical guidelines. Proprietary information, submitted by a requestor, not available to the public shall not be considered. Medicare data considered as part of the evidence review for an LCD shall be reported in the evidence summary. The reported data shall comply with Medicare Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule data disclosure requirements by using aggregate level information, such as aggregated statistics on Medicare beneficiary or provider utilization. The review shall include a summary of all the evidence used to support the determination, which may be grouped by type of evidence evaluated.

MACs shall list all articles and sources that led to the LCD in the Bibliography. The citations shall be consistent with the American Medical Association (AMA) Manual of Style.

MACs shall explain the rationale that supports their coverage determination of covered, non-covered, or limited coverage. The rationale is the reasoning leading to the coverage determination.

If it is appropriate for a MAC to provide coding/billing information to help implement the coverage policy, MAC shall publish the coding/billing article at the same time they publish the proposed LCD.

13.5.4 – Reasonable and Necessary Provisions in LCDs **(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)**

An item or service may be covered by a contractor LCD if:

- *It is reasonable and necessary under 1862(a)(1)(A) of The Act. Only reasonable and necessary provisions are considered part of the LCD.*

Reasonable and Necessary

Contractors shall determine and describe in the LCD the circumstances under which the item or service is reasonable and necessary under 1862(a)(1)(A). Contractors shall determine if evidence exist to consider an item or service to be reasonable and necessary if the contractor determines that the service is:

- *Safe and effective;*
- *Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and*
- *Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*

- *One that meets, but does not exceed, the patient's medical need; and*
- *At least as beneficial as an existing and available medically appropriate alternative.*

13.5.5 - Public Comment

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

MACs are required to provide a minimum of 45 calendar days for public comment on all proposed LCDs. MACs shall respond to all timely received public comments, and may group similar comments and responses in logical categories in the RTC article.

13.5.6 - Final Decision

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

MACs shall finalize or retire all proposed LCDs within a rolling year of publication date of the proposed LCD on the MCD (365 days). After the close of the comment period and the required meetings, the MACs shall publish a final LCD to the MCD. MACs shall link from their contractor website to the final LCD on the MCD. As stated earlier, the MAC shall also respond to all comments received, via the RTC article which shall be published on the MCD and be related to the LCD. The RTC article shall be displayed at the same time as the final LCD.

MACs shall notify the public that a final decision has been published and provide the Web link to the final decision. MACs may use several tools at their disposal to educate providers, including the “What’s New Report” on the Medicare Coverage Database, setting up email listservs, or other 508 compliant and accessible means to inform stakeholders.

13.6 - LCD Record

(Rev: 854; Issued: 01-11-19; Effective: 09-26-18; Implementation: 01-08-19)

The LCD record shall be maintained by contractors for a minimum of 6 years and 3 months from the date the LCD is retired. Contractors shall have a mechanism for archiving retired LCDs. This mechanism shall also allow the contractor to respond to requests and retrieve the LCD record. After 6 years and 3 months from the date the LCD is retired, the LCD record shall be destroyed. However, contractors shall not destroy the LCD record if it relates to a current investigation of litigation/negotiation; ongoing Workers’ Compensation set aside arrangements; or documents which prompt suspicions of fraud and abuse of items or services. This will satisfy evidentiary needs and discovery obligations critical to the agency’s litigation interests.

Medicare Program Integrity Manual

Exhibits

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