CQRC COUNCIL FOR QUALITY RESPIRATORY CARE

July 30, 2021

Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD

Re: Proposed Decision Memo for Home Use of Oxygen and Home Oxygen Use to Treat Cluster Headaches (CAG-00296R2)

Dear Ms. Syrek Jensen:

On behalf of the members of the Council for Quality Respiratory Care (CQRC), I want to thank you for the opportunity to provide comments on the Proposed Decision Memo for Home Use of Oxygen and Home Oxygen Use to Treat Cluster Headaches (CAG-00296R2) (Proposed Decision Memo). In brief, the CQRC supports expanding patient access to oxygen used outside of institutional settings (home oxygen), but is concerned that the practical implications of the proposal to eliminate the Certificate of Medical Necessity (CMN) and subject all claims to only medical record audit review could result in the vast majority of patients – both chronic and acute – losing access to these therapies. To address this concern, we ask that the final coverage policy:

(1) finalize the expansion of home oxygen to include acute and chronic patients;

(2) finalize the proposal to eliminate "chronic stable state" requirements, remove language that requires patients to try other therapies and fail on them before being allowed to receive home oxygen, and eliminate the list of specific conditions necessary to quality for home oxygen therapy; and

(3) rely upon the physician's prescription to establish medical necessity, as is done with coverage and reimbursement for pharmaceutical products, and eliminate the use of the medical record of the prescriber for medical necessity audits.

Eliminating medical record review is consistent with the overall goal of making sure that the right patient gets the right equipment at the right time. It also supports the Administration's health equity initiative. During the pandemic, it became clear that individuals in communities of color are being under-prescribed medically necessary home respiratory therapy.[1] Our members' experience, which CMS contractors verify annually

[1]Roni Caryn Rabin. "Pulse Oximeter Devices Have Higher Error Rate in Black Patients." *New York Times* (Dec. 22, 2020). https://www.nytimes.com/2020/12/22/health/oximeters-covid-black-patients.html. accessed July 17, 2022; see also Food and Drug Administration. "Pulse Oximeter Accuracy and Limitations: FDA Safety Communication." (Feb. 19, 2021). https://www.fda.gov/medical-devices/safety-communications/pulse-oximeter-accuracy-and-limitations-fda-safety-communication. accessed July 17, 2021.

through the CERT reports, shows that the medical record review does not identify patients who fail to meet the medical necessity requirements, but rather it focuses on "errors" that physicians make in their medical notes. Because physician reimbursement is not affected by these reviews, there is no incentive for them to modify their practices. Thus, it is unclear what benefit there is to the Medicare program for this process to continue.

If CMS seeks additional documentation to support the prescription, we urge the adoption of the home oxygen templates, modified to meet the new requirements set forth in the Proposed Decision Memo. (See Appendix) These documents to which the physician attests provide the information necessary to support a claim in a straight-forward and objective manner. They may be especially helpful to protect access for Black patients whose physicians prescribe oxygen, but whose pulse oximetry test exceeds the levels listed in the Proposed Decision Memo. Relying on the medical record instead would be like playing Russian Roulette with these patients because there is no guarantee the prescribing physician will hit the "magic words" a contractor seeks to approve the claim.

If CMS were not to adopt the use of these documents and not eliminate medical record review, we ask that CMS maintain and reinstate the Certificate of Medical Necessity (CMN) as the document used to establish medical necessity. It is the only objective document that suppliers are able to rely upon during the audit and appeals process that will support a patient's access to the therapy that his/her physician has prescribed. Without some level of objective support outside of the medical record, the denial rate will result in suppliers leaving the Medicare program. Simply put, suppliers cannot operate a business with nearly 80 percent of their claims locked in the audit and appeals process because of flaws in a document they do not create and over which they have no influence.

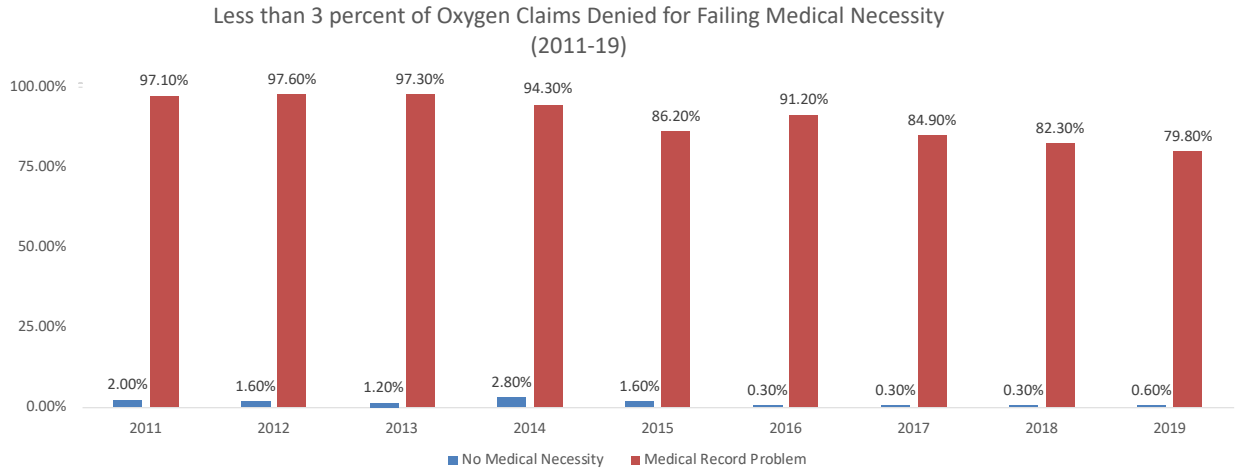
I. The CQRC supports expanding patient access to oxygen and oxygen equipment used in and outside of the home through the coverage of home oxygen therapy for individuals with acute conditions.

During the pandemic, the CQRC member organizations have been on the front-lines of the health care crisis serving patients in their homes. Our members have worked diligently to address the overwhelming need for oxygen therapy outside of hospitals and other facility settings, often at great risk to their employees. As CMS recognized in the flexibilities it established during the public health emergency, individuals with an acute condition that requires oxygen therapy can often be treated effectively and more efficiently in the home setting. During the last 16 months, the CQRC has shared with CMS the importance of these flexibilities, especially in terms of patient access and improved outcomes. We are, therefore, pleased that CMS has proposed modifications to the NCD for Home Oxygen Use that apply the lessons learned and experience gained during the pandemic about the benefits of providing stationary and/or portable oxygen in the home setting to individuals whose health care professional prescribes it for them.

The CQRC supports finalizing the proposal to expand the coverage of oxygen and oxygen equipment in the home for short-term, as well as long-term use, in both acute and chronic diseases of respiratory and non-respiratory origin, as is medically necessary. (Page 10). We agree with the conclusion noted in the Proposed Decision Memo that "this expansion is appropriate as it will remove limitations on reasonable and necessary treatments with home oxygen and oxygen equipment for beneficiaries. As seen during the PHE, this will also give physicians more options to provide the best course of treatments." (Pages 10-11). This expansion is an important step forward in getting the right treatment to the right patient at the right time.

II. The CQRC supports the proposed changes to the 1993 NCD 240.2 to implement the expansion of access for patients, but not those proposals that would result in practical barriers to access by providing contractors with more discretion when evaluating patients' medical necessity.

To effectuate this expansion of coverage, CMS correctly proposes to make several changes to the 1993 NCD 240.2. The CQRC supports several of these proposals, but is concerned with shifting from objective criteria to contractor discretion. Our concern arises from our experience with medical record review during the last 10 years. As the chart of data from the CERT Reports[2] below demonstrates, there is no evidence of fraud or abuse in terms of patients getting home oxygen who do not medically require the equipment, supplies, and services. Instead, the flaws sit with how clinicians complete their medical record.



[2]CMS. "Medicare Fee-for-Service Supplemental Improper Payment Data." (2011-2019). https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/CERT-Reports. Accessed July 15, 2020.

As the chart shows, less than 1 percent of the claims denied since 2016 have been because a patient did not medically need the therapy. Yet, during the same period, 80-90 percent of home oxygen claims were denied because of a problem with the way the prescriber – not the supplier – documented the patient's condition in the medical record.

Unless CMS were to hold clinicians financially accountable for these "errors," nothing will change. To date, suppliers have been able to remain in the Medicare program because the CMN can be the basis for the Administrative Law Judge overturning the denials. If contractor discretion becomes the standard and the CMN is eliminated without being replaced by the physician's prescription and/or the objective templates, the uncertainty of being reimbursed for providing the equipment and supplies will not allow suppliers to continue working with the Medicare population.

The CQRC encourages CMS to proceed cautiously, use the physician prescription alone or with the objective oxygen templates (as modified to address the expansion in coverage), and eliminate the unpredictable, time consuming, and costly (to the government and suppliers) medical record review process. The tone of the Proposed Decision Memo seems to support relying upon physician discretion and judgment. We encourage the agency not to allow federal contractors who have never examined the patient to second-guess the treating physician's decision.

A. The CQRC supports the reliance on clear, objective documentation of test results as the basis for establishing medical necessity for home oxygen therapy.

The CQRC supports the new language in Section B of the 1993 NCD 240.2 that states: "Initial claims for oxygen therapy for hypoxemic patients must be based on the results of a clinical test that has been ordered and evaluated by the treating practitioner." (Page 19). We also support defining the tests to be used as an arterial blood gas (ABG) or pulse oximetry. (Page 19). Most physicians do not have the ability to draw and analyze arterial blood gases in their offices. Because an ABG must be performed in a hospital or outpatient setting, it is important that patients have the option to be evaluated in lower-cost settings, such as their physicians' office, qualified provider, or supplier of laboratory services. (Page 19). Given the concerns with pulse oximetry tests under-reporting low oxygen saturation levels, we appreciate the agency's nuanced approach to the continued use of both the ABG and pulse oximetry testing to support claims for home oxygen therapy.

Having both the ABG and pulse oximetry testing options available to patients is important to address the ability of patients, especially those from communities of color, to access home oxygen therapy. As the pandemic highlighted, communities of color and those with lower socio-economic status face significant barriers to receiving health care services. Early access to treatment to manage the disease is not always available. In addition, fear and distrust of the medical establishment in many communities of color result in at-risk individuals not seeking medical care in a timely manner. To protect access and promote

health equity, it is essential to maintain testing options outside of the hospital setting and to provide clear and objective criteria that defers to physician/clinical judgment, not federal contractor discretion, when accessing claims for home oxygen therapy.

A recent study in England highlighted how these systemic challenges can affect the ability of Blacks to receive long-term oxygen therapy. It is not a stretch to imagine a similar problem in the context of acute oxygen therapy as well. In this study, researchers reported that several previous epidemiological studies found that long-term home oxygen therapy (LTOT) was under-prescribed. The researchers hypothesized that one reason for the under-prescribing was the unavailability to physicians of a measure of arterial oxygenation needed to fulfil the defined prescription criteria. They believed that the provision of a non-invasive measure of oxygenation could improve detection of hypoxic subjects and increase appropriate prescribing. In testing their hypothesis, the researchers relied upon pulse oximetry testing. During their study, several patients refused the ABG test, but were willing to have the pulse oximetry test performed. The results of the study demonstrated the value of pulse oximetry for those patients who cannot or will not go to a hospital setting for an ABG test.[3]

The results of this study are particularly important given the challenges our country faces in overcoming the distrust of Blacks and Hispanics with regard to the health care system generally. Its findings are even more disturbing when one takes into account that air pollution – a leading cause of respiratory diseases and conditions – disproportionately affects Blacks and Hispanics. Their exposure is 1.5 times more than the overall population.[4] Such exposure can lead to chronic respiratory conditions, such as COPD. COPD is the fourth leading cause of death in the United States and the nineth most prevalent chronic condition in the Medicare population. It affects 1 in 8 American Indian/Alaska Natives; 1 in 10 Blacks/African Americans; 1 in 12 Hispanics; and 1 in 15 Asian/Pacific Islanders. Yet, these numbers likely under-report the actual burden of COPD and other respiratory diseases in communities of color.

Given their greater risk for respiratory conditions requiring the use of home oxygen therapy, often due to socio-economic factors and lack of consistent primary care to manage chronic diseases, it is important that non-invasive testing options be allowed to serve as the basis for prescribing home oxygen therapy. Shifting away from the current policy that allows pulse oximetry toward a policy requiring ABGs would be taking a step backward

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[3]Roberts CM, Franklin J, O'Neill A, Roberts RP, Ide J, Hanley ML, Edwards J. Screening patients in general practice with COPD for long-term domiciliary oxygen requirement using pulse oximetry. Respir Med. 1998 Nov;92(11):1265-8. doi: 10.1016/s0954-6111(98)90226-8. PMID: 9926138.

[4]Christopher W. Tessum, Joshua S. Apte, *et al.* "Inequities in Consumption of Goods and Services Adds to Racial-Ethnic Disparities in Air Pollution Exposure." Institute of Medicine. 116 *Proc. Natl. Acad. Sci. USA* 6001-06 (2019); *See also,* National Academies of Science. *Toward Environmental Justice: Research, Education, and Health Policy Needs*. Washington, DC: The National Academies Press. https://doi.org/10.17226/6034.

rather than forward at the very time most areas of health care are working to find less-invasive ways to treat patients outside of the hospital setting.

The CQRC recognizes the challenges of relying upon pulse oximetry testing, given the concerns highlighted during the pandemic that pulse oximetry test results, especially when the test is administered in the home, may under-report serious oxygen saturation levels. The CQRC supports the additional language that recognizes that skin pigmentation can affect the test results, as can the altitude level at which the patient lives. (Page 20). In both instances, the pulse oximetry tests may register higher levels of oxygen saturation than is actually true. Thus, if used alone and without clinical judgment, a patient's risk for respiratory failure may go unnoticed.

We appreciate that CMS is not proposing to eliminate the use of pulse oximetry test results expressly, but are concerned that the language of the Proposed Decision Memo may result in federal contractors denying claims based on these test results. If medical record reviews were to continue, the lack of appropriately specified medical record notes coupled with the language in the Proposed Decision Memo around "sophisticated audits of the medical record" will result in complete contractor discretion and nearly all claims being denied. Without an objective document, such as the prescription and/or the oxygen templates, as the basis for claims review, the effort to expand access to home oxygen therapy the Proposed Decision Memo envision will have the opposite result of eliminating access to this life-sustaining therapy.

B. The CQRC seeks clarification on defining the time of need.

The CQRC also seeks clarification with regard to the proposal that requires the qualifying blood gas studies be performed "at the time of need." The Proposed Decision Memo states:

> The 'time of need' means during the patient's illness when the presumption is that the provision of oxygen will improve the patient's condition in the home setting, whether that condition represents a long-term chronic illness or an expected short-term recovery from an acute disorder. For an inpatient hospital patient, this would ordinarily be (as currently stated in the 1993 NCD) within 2 days of discharge. For those patients whose initial oxygen prescription does not originate during an inpatient hospital stay (such as individuals with CH), the time of need would logically be during the period when the treating practitioner notes signs and symptoms of illness that may be relieved by oxygen in the patient who is to be treated at home.

(Page 13). As we read this language, we believe the statement pertains only to the initiation of oxygen therapy. We request that CMS clarify this statement so that federal contractors do not create an ongoing requirement outside of the existing recertification

process for additional patient testing. Such a clarification would reduce the potential burden on clinicians, patients, and suppliers.

C. The CQRC supports removing requirements related to chronic conditions to support expanding access to home oxygen therapy to patients with acute conditions.

The CQRC also supports the proposals to eliminate the "chronic stable state" requirements, language that requires patients to try other therapies and fail on them before being allowed to receive home oxygen, and the list of specific conditions necessary to quality for home oxygen therapy. As CMS recognizes, these labels are no longer necessary once coverage is expanded to include acute patients. Eliminating the "tried and failed" language is particularly important to making sure that the right patient is getting the right therapy at the right time. No one wants to see their family member or friend struggle through alternative therapies that the physician and patient know will not help the patient or address the underlying medical problem just to satisfy a paperwork requirement with the Medicare program. We applaud CMS for proposing to remove this especially troubling requirement.

In addition, we seek clarification about how CMS plans to instruct the federal contractors to distinguish between acute and chronic patients when it comes to recertification. Without such clarity, the practical result is that all patients will be required to return to their physician as if they were acute patients in 90 days of the first prescription. This requirement would create an added burden to patients in terms of time and coinsurance obligations. It would also place a burden on healthcare practitioners who must see the patients for requalification purposes. To address this concern, the CQRC recommends that the contractor use the Face-to-Face template, which must be completed within six months of the initial prescription to establish the medical need for the device. We also request that CMS allow suppliers to obtain an Advance Beneficiary Notice of Noncoverage (ABN) at the time of set up, so that any patient using home oxygen who does not qualify under the recertification would be able to maintain the equipment in their home and chose to pay the supplier directly without a gap in service or another visit to the physician.

III. To protect the expanded access to medically necessary home oxygen therapy, the CQRC requests that CMS address the documentation requirements for coverage and identify clear, objective documentation requirements that do not require the review of individual patients' medical records.

We applaud CMS for extending coverage of home oxygen therapy to acute patients. It is important that federal contractors not be allowed to substitute their judgment for that of the prescribing clinician ordering the equipment. Medical record review has allowed that substitution to disrupt this area of health care during the last 10 years. While

suppliers have put patients first and tried to work through this challenging situation, they have succeeded only because the ALJs recognize the value of the objective CMN.

We recognize that the CMN presents many challenges to the program, some of which have very little to do with patient need and are more systemic or programming issues. To that end, we understand that it may be appropriate to stop using this particular document given that it has morphed from a statement supporting medical necessity to trying to accomplish other goals. However, a clear, objective document is needed to allow suppliers to know when a patient will or will not qualify for home oxygen. It is untenable to ask suppliers to set up equipment in a patient's home, provide education about operating the device, provide 24/7 access to live patient support, and deliver supplies as needed if they cannot predict which claims will be paid and which ones denied.

We believe that the language of the Proposed Decision Memo supports deferring to the prescribing clinician if the test results outlined in the proposed NCD are met. We also believe it supports deferring to the clinician when the pulse oximetry results may exceed the thresholds in the proposed NCD, but in the physician's judgement the results may be distorted because of the patient's race or ethnicity. If our understanding is correct, then it seems to follow that CMS should require contractors to substantiate claims based solely on the clinician's prescription. Medicare pays for prescription drugs in this manner. It is not clear why prescriptions for oral drugs should be given greater deference than prescriptions for oxygen, which is also classified as a drug.

To the extent CMS believes additional documentation is necessary to support home oxygen claims, the CQRC recommends that the oxygen templates be used. In the Appendix, we have included suggested revisions to these templates based on our understanding of the Proposed Decision Memo and its goals. The templates would be completed by the prescribing clinician and constitute an attestation that the information is accurate. CMS may want to explore how the attestation as a claim of accurate reporting to the federal government could subject the prescribing clinician to the False Claims Act requirements as well or simply exercise the authority to audit the clinician's claims as outlined in the Medicare Program Integrity Manual §§ 3.2.3 & 3.3.2.1.1C. Rather than subjecting claims to medical record review and the subjective interpretation by individual contractors, the templates provide the specific information that prescribing clinicians must complete in order for the claim to the reimbursed. The templates provide clarity, objectivity, and predictability. We recommend that CMS work with OMB to have the forms officially approved before the proposed NCD modifications take effect.

IV. The CQRC requests CMS maintain the clarification that Respiratory Therapist Services are not covered under the DME benefit.

While the CQRC understands that the DME benefit does not include Respiratory Therapist services, maintaining the current statement in the revised NCD is important. (Page 14-15). Respiratory Therapist services are the standard of care and an essential part

of the services that patients with respiratory conditions and diseases need. Continuing to reference that these services are outside the DME benefit acknowledges their role in patient care, while clarifying that they are outside the scope of this particular benefit.

V. Conclusion

The CQRC appreciates the opportunity to provide comments on the Proposed Decision Memo. We applaud the decision to expand access to home oxygen therapy. It is important that this expansion be practically achieved as well by eliminating medical record review and relying upon a clinician's prescription alone or with the completed oxygen templates as modified to address the expanded coverage. We look forward to working with you on this coverage process. Kathy Lester, the CQRC Executive Director, will be in touch to request a meeting to discuss our comments in more detail. Please do not hesitate to contact her in the meantime if any questions arise.

Sincerely,

Chairman
Council for Quality Respiratory Care

Appendix: Suggested Modifications to the Oxygen Templates

The CQRC supports the three oxygen templates as recommended in the letter. We suggest the following modifications to these documents to incorporate the proposals outlined in the Proposed Decision Memo and the recommendations made by the CQRC in this letter. In brief, the CQRC recommends:

Oxygen Order Template Guidance

- Eliminate the text that indicates the template is voluntary/optional.

- Modify the "Purpose" section to read: "The purpose of the template is to establish the required elements for a Medicare beneficiary coverage for home oxygen therapy, as well as documentation to support a claim for reimbursement. It should be completed by the prescribing clinician/clinician's staff and provided to the DME supplier at the time the therapy is ordered. This template meets the requirements for Standard Written Order (SWO). This template is available to the clinician and can be kept on file with the patient's medical record or can be used to develop an order template for use with the system containing the patient's electronic medical record. This document must be sent to the DME supplier."

- Modify the "Patient Eligibility" section to read: "Eligibility for coverage of home oxygen therapy under Medicare requires the ordering physician or allowed Non-Physician Practitioner (NPP) to complete this template and the Lab Testing Template (if the lab results are not included on this template) to establish that coverage criteria are met, as well as documentation to support a claim for reimbursement. This helps to ensure the oxygen equipment and services to be provided are consistent with the physician's prescription. This template is to be used with the 'Home Oxygen Therapy Laboratory Test Results Template.'"

- Modify the list of items in the "What needs to be specified on the order" to align with the requirements for the Standard Written Order:

    - Beneficiary's name or MBI
    - Ordering practitioner's name or NPI
    - Order Date
    - Practitioner's signature
    - Whether the patient's need is acute or chronic
    - O2 Flow Rate
    - Estimated frequency and duration of use (e.g., 2L/minute, 10 minutes/Hour, 12 Hours/Day) and
    - Duration of need (e.g., 6 Months, 12 Months, 99 Months/Lifetime).
    - General description of the item ordered (*e.g.* stationary/portable oxygen, a HCPCS code, a HCPCS code narrative, or a brand name/model number)

    - Any additional supplies/accessories

- Modifications to the actual template include:
    - Eliminating the text that indicates the template is voluntary/optional
    - Eliminating the frequency of O_2 saturation monitoring.
    - Add acute or chronic need

Oxygen Laboratory Test Results Template

- Eliminate the text that indicates the template is voluntary/optional.

- Modify the "Purpose" section to read: "The purpose of the template is to establish the required elements for a Medicare beneficiary coverage for home oxygen therapy, as well as documentation to support a claim for reimbursement. It should be completed by the prescribing clinician/clinician's staff and provided to the DME supplier at the time the therapy is ordered. This template is available to the clinician and can be kept on file with the patient's medical record or can be used to develop an order template for use with the system containing the patient's electronic medical record. This document must be sent to the DME supplier."

- Modify the "Patient Eligibility" section to read: "Eligibility for coverage of home oxygen therapy under Medicare requires the ordering physician or allowed Non-Physician Practitioner (NPP) to complete the Oxygen Order Template (and this form if the testing result are not included on the order template) to establish that coverage criteria are met, as well as documentation to support a claim for reimbursement. This helps to ensure the oxygen equipment and services to be provided are consistent with the physician's prescription. This template is to be used with the "Home Oxygen Therapy Order Template, if the testing result are not included on the order template."

- Eliminate after "exercise" the phrase "provided there is evidence of:" and accompanying bullets.

- Eliminate the "Group III criteria (NOT COVERED):" section, if the CMN were eliminated.

- Modifications to the actual template include:
    - Eliminating the text that indicates the template is voluntary/optional.

Oxygen F2F Encounter Template

- Eliminate the text that indicates the template is voluntary/optional.

- Modify the "Purpose" section to read: "This template is designed to document the Face-to-Face (F2F) encounter for Medicare home oxygen therapy eligibility and coverage, when a F2F encounter is required, as well as documentation to support a claim for reimbursement when a F2F encounter is required. This template is available to the clinician and can be kept on file with the patient's medical record. This document must be sent to the DME supplier."

- Modify the "Patient Eligibility" section to read: "Eligibility for coverage of home oxygen therapy under Medicare requires the ordering physician or allowed Non-Physician Practitioner (NPP) to complete the Oxygen Order Template (and the Laboratory Test Template if it testing results are not on the Order Template) to establish that coverage criteria are met, as well as documentation to support a claim for reimbursement. This helps to ensure the oxygen equipment and services to be provided are consistent with the physician's prescription. This template is to be used with the "Home Oxygen Therapy Order Template."

  The physician or an allowed NPP must certify (attest) that the patient meets criteria for eligibility and coverage in accordance with the requirements of the National Coverage Determination (NCD) for Home Use of Oxygen – 240.2. This template is to be used with the "Home Oxygen Therapy Laboratory Test Results Template" and "Home Oxygen Therapy Order Template".

- Modify "Basis for Certification of Home Oxygen Therapy?" to read: "The Order Template and the Laboratory Test Results Template must the requirements of the National Coverage Determination (NCD) for Home Use of Oxygen – 240.2."

- Modifications to the actual template include:
  - Eliminating the text that indicates the template is voluntary/optional.
  - Eliminating after "exercise" the phrase "provided there is evidence of:" and accompanying bullets.
  - Eliminating the question "Is patient in a chronic stable state?"