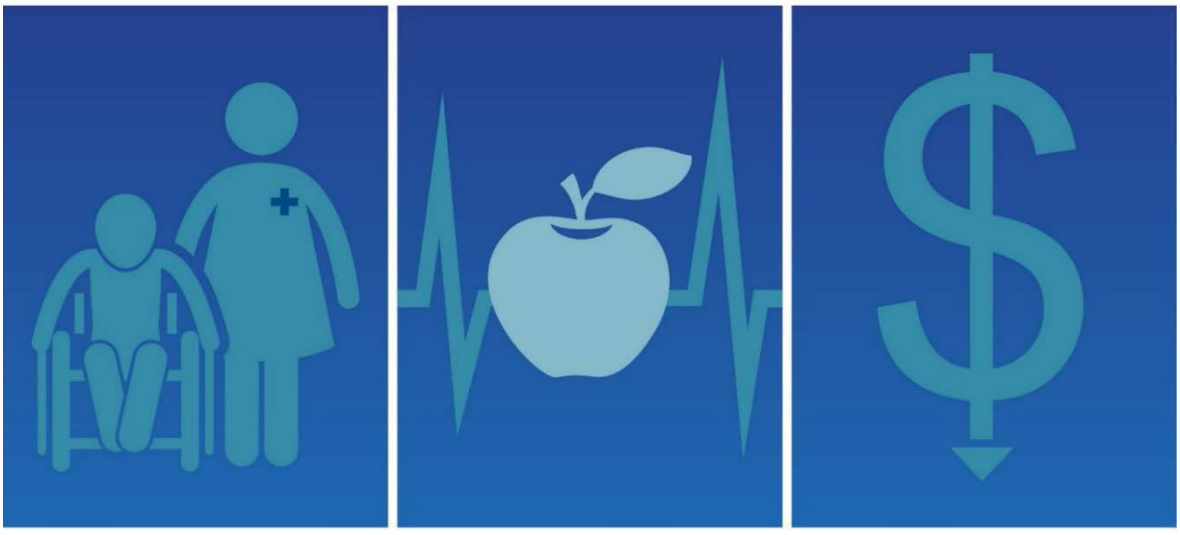
MATHEMATICA
Policy Research

Interim Report for the Evaluation of Medicare Prior Authorization Model for Non-emergent Hyperbaric Oxygen (HBO)

HHSM-500-2014-00034
June 2018

Andrew Asher
Kara Contreary
Geraldine Haile
Kristen Purcell
Rebecca Morris
Jared Coopersmith
Andrea Goldstein



Better Care, Healthier People, Smarter Spending

Submitted to:

U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244
Attention: William Buczko, PhD, Project Officer

Submitted by:

Mathematica Policy Research
1100 1st Street, NE 12th Floor
Washington, DC 20002-4221
Telephone: (202) 484-9220
Facsimile: (202) 863-1763

The statements contained in this report are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services.

CONTENTS

EXECUTIVE SUMMARY IX

I. INTRODUCTION 1

Model background 1

The evaluation 4

Data sources and outcome measures 4

II. QUANTITATIVE DATA ANALYSIS METHODS 9

Data and population 9

Analytic approach 12

III. QUALITATIVE DATA COLLECTION AND ANALYTIC METHODS 15

Overview 15

IV. QUANTITATIVE ANALYSIS RESULTS 17

Domain 1: Utilization and expenditures 17

Domain 2: Quality of care 26

Domain 5. Improper payment and claims denials 31

V. QUALITATIVE ANALYSIS RESULTS 33

Domain 1. Utilization and expenditures 34

Domain 2. Quality of care 35

Domain 3. MAC program operations 39

Domain 4. Providers 42

Domain 6. Scalability/implications 45

CMS CPI Perspectives 46

CONCLUSION 49

Study limitations 50

REFERENCES 51

This page has been left blank for double-sided copying.

TABLES

ES.A. Findings xi

I.1. Conditions applicable to HBO prior authorization 3

I.2. Evaluation research questions and data source 5

IV.1. Number of providers billing Medicare for HBO for beneficiaries with included conditions, 2012-2016 by state 17

IV.2. HBO utilization by first diagnosis 18

IV.3. Impact of prior authorization on quarterly HBO utilization and cost among beneficiaries with diabetic lower extremity wounds 23

IV.4. Impact of prior authorization on quarterly HBO utilization and cost among beneficiaries with any included condition 25

IV.5. Impact of prior authorization on quality of care and adverse outcomes among beneficiaries with diabetic lower extremity wounds 28

IV.6. Impact of prior authorization on quality of care and adverse outcomes among beneficiaries with any included condition 29

IV.7. Impact of prior authorization on adverse outcomes related to diabetic lower extremity wounds 30

IV.8. Impact of prior authorization on quarterly beneficiary claims denials, by quarter after model implementation 31

V.1. Online survey question asks “Thinking about your patients who have delayed or canceled scheduled HBO treatments because they were not affirmed for HBO therapy, which of the following conditions were they being treated for?” [Select all that apply] 36

This page has been left blank for double-sided copying.

FIGURES

IV.1. Probability of HBO utilization among beneficiaries with diabetic lower extremity wounds, by quarter 19

IV.2. Probability of HBO utilization among beneficiaries with an included condition, by quarter.....20

IV.3. HBO expenditures per beneficiary with diabetic lower extremity wound, by quarter 21

IV.4. HBO expenditures per beneficiary with an included condition, by quarter.....22

This page has been left blank for double-sided copying.

EXECUTIVE SUMMARY

Overview

In 2015, the Centers for Medicare & Medicaid Services (CMS) launched a three-year Medicare Prior Authorization model for hyperbaric oxygen (HBO) therapy in selected states with high improper payment rates compared to other states. Prior authorization is a utilization management strategy intended to reduce improper payments by requiring claims for services to be reviewed by a health care payer for compliance with coding, billing, and coverage rules (including medical necessity) before services are rendered to beneficiaries and claims are submitted for payment. Thus, prior authorization both promotes general cost containment and control of waste, fraud, and abuse.

The purpose of the model is to test whether prior authorization can reduce Medicare expenditures by reducing the provision of non-covered outpatient HBO therapy without adversely affecting access to or quality of care for beneficiaries. Non-emergent hyperbaric oxygen provides a therapeutic dose of oxygen by exposing a patient's entire body to pure oxygen under increased atmospheric pressure. The resulting higher oxygen concentration in the bloodstream has the potential to improve wound healing (for wounds, for example, from diabetic neuropathy or soft tissue damage from radiation treatment). HBO therapy is a covered service under Medicare Part B if the receiving beneficiary meets specified criteria. Past audits of Medicare claims and medical records reveal a high improper payment rate for HBO therapy; a large share of these improper payments have been for HBO treatments for conditions and prior treatments not adequately supported by documentation.

Implementation of the model began in April 2015 in Michigan, followed by Illinois and New Jersey in August 2015[1].

The evaluation

CMS contracted with Mathematica Policy Research and Provider Resources, Inc. (PRI), to conduct an evaluation of CMS's prior authorization model for non-emergent HBO therapy in Illinois, Michigan, and New Jersey. The goal of the evaluation is to rigorously assess prior authorization as a means of reducing payments for medically unnecessary services, thereby reducing costs and improper payments while maintaining or improving the quality of care provided to beneficiaries. In this report, we provide findings to date from our evaluation of the HBO prior authorization model.

We organized the guiding research questions for the evaluation around five domains:

- **Domain 1. Utilization and expenditures.** How does the prior authorization model affect Medicare service utilization and expenditures? Does the model realize savings for the Medicare program?

[1] The model ended on February 28, 2018, and there are no current plans for it to be extended or expanded.

- **Domain 2. Quality of care.** How does the prior authorization model affect the quality of and access to care for Medicare beneficiaries?
- **Domain 3. Program operations.** How does the prior authorization model affect Medicare program operations? What is the impact of the model on Medicare Administrative Contractor (MAC) operations?
- **Domain 4. Providers.** How does the prior authorization model affect non-emergent HBO therapy providers' behavior and satisfaction? What is the impact of the model on providers' operations? Do providers change practices in response to the model and, if so, how?
- **Domain 5. Improper payment and denials.** Does prior authorization affect improper payment rates or the rate of claim denials?

The evaluation uses a mixed-methods approach that combines quantitative and qualitative data analysis to (1) measure overall service utilization, cost, quality, and access impacts and (2) understand how the model's implementation is affecting stakeholders. The quantitative analysis design includes beneficiaries in the treatment or comparison group states with any of five conditions.[2] The five conditions examined are a subset of a larger group of conditions that qualify beneficiaries for HBO and are distinguished by a requirement that HBO is received only as an adjunct service to standard therapy. Beneficiaries with any of these five conditions are included in the study population from their time of diagnosis until their death, a move out of their (treatment or comparison) state of residence, or exit from fee-for-service Medicare.

The quantitative analysis uses both descriptive and multivariate analysis methods, specifically difference-in-difference models, to estimate the model's impact. For this report, we analyze quarterly data on beneficiaries from April 2012 through December 2016. We estimate model effects by comparing the change over time in key outcomes between the pre-model (before April 2015) and model (April 2015 and later) periods in the three model states to change in those periods for a matched set of comparison states.

The qualitative analysis relies on structured interviews with Medicare Administrative Contractor (MAC) personnel, who are responsible for administering the HBO model in Illinois, Michigan, and New Jersey under contract to CMS. We conducted interviews with MAC personnel 12 to 16 months after model launch to understand more fully the experience of implementing the prior authorization model on Medicare program operations. In addition, from April through May 2017, we conducted site visits to HBO facilities in model states. During the site visits, we conducted semi-structured interviews with HBO facility staff and beneficiaries. Lastly, we fielded an online survey with HBO facilities in model states to help validate the key themes that emerged from interviews and site visits. Following qualitative data collection and the submission of our draft report, we conducted a semi-structured, in-person interview with three senior staff members from the CMS Center for Program Integrity (CPI), which is responsible for prior authorization efforts, to assess the HBO prior authorization model's implementation and operation, their perceived impact and effectiveness of the model, and CMS' reasons for not extending or expanding the model beyond the planned February 28, 2018 ending date. Together, data gathered from MACs, HBO facility staff, CMS CPI staff, and beneficiaries are meant to

[2] Table I.1 in the Chapter I (on page 3) lists and provide information on these required conditions.

provide CMS with an understanding of the model's operations and stakeholder experiences, while also supplementing the quantitative analysis assessment of the model's ability to reduce improper utilization and costs while maintaining quality and access to care.

Findings

Our findings on the effects of prior authorization for HBO services suggest that the model was effective in reducing HBO utilization and cost. We also found that total Medicare expenditures decreased, although this effect was not statistically significant. There is no evidence at this stage suggesting that the model reduced quality of care or increased adverse events. We did not find that the model was associated with decreased quality of care or increased incidence of adverse outcomes for both beneficiaries with diabetic lower extremity wounds and beneficiaries with any included condition. However, stakeholders reported delays in some beneficiaries' receipt of HBO treatment.

Specific groups of stakeholders also have divergent views about the model's effectiveness. MAC staff believe the prior authorization model was implemented relatively smoothly, with few continuing difficulties. Some HBO providers, in contrast, report several types of challenges, including additional administrative burden, inconsistent application of medical necessity guidelines, and significant difficulty in understanding the pre-existing documentation requirements enforced under the model. Ordering providers also believe that they spend additional resources on tests needed to justify HBO treatment.

In Table ES.A, we present findings for the evaluation's core questions, using quantitative and qualitative data from model states. In the body of the report, we discuss the findings and the supporting data and analyses in detail.

Table ES.A. Findings

Domain 1: Utilization and expenditures **Prior authorization reduced HBO service use and Medicare expenditures.**
• The estimated probability of HBO utilization, number of HBO treatments, and average HBO expenditures all decreased for the population of beneficiaries with any condition subject to prior authorization as well as for our focal analysis group: beneficiaries with diabetic lower-extremity wounds. • HBO expenditures decreased by nearly 40 percent for both of these groups. • The decrease in HBO service use does not appear to be offset by increased spending on other wound care services. • At the same time, the observed decrease on total Medicare expenditures is not statistically significant, possibly because HBO services comprised a small fraction of total expenditures for Medicare services. • These findings are consistent for rural/urban and dual-eligible/Medicare-only subgroups. • The qualitative analysis supports these findings, as both MAC and provider staff interviewed report a reduction in the number of Prior Authorization Requests (PARs) submitted for ineligible beneficiaries, and HBO provider interviews suggest lower levels of utilization in some settings.

Domain 2: Quality of care

Prior authorization did not appear to reduce the quality of care received by beneficiaries or increase adverse events. Stakeholders report some delays in beneficiaries receiving timely access to care in the early phases of the model.

- Prior authorization does not appear to either reduce the quality of care received by beneficiaries or increase adverse events. The probability of an emergency department visit, probability of an unplanned hospitalization, and probability of death each decreased significantly. These findings are consistent across all states and subgroups we examined.
- HBO staff report that the number of beneficiaries whose PAR was non-affirmed for HBO therapy based on ineligibility for the service is small, but the number of beneficiaries whose PARs are initially non-affirmed, delayed, and ultimately affirmed is substantial. These same staff members believe that the delay in obtaining final PAR decisions may result in delayed access to care for some beneficiaries.
- HBO providers and MAC staff report that the delays in obtaining final PAR determinations often result from missing or inadequate documentation, which becomes less of an issue over time as providers become more familiar with the pre-existing documentation requirements enforced under the model.
- Interviewed beneficiaries who had been approved for treatment do not report negative effects on access to care or quality of care.

Domain 3: MAC Program operations

MACs report few challenges.

- In interviews, MAC staff report efficient and effective model implementation. One of the three MACs reported that it drew directly on processes developed during its participation in implementation of the Repetitive Scheduled Non-Emergent Ambulance Transport (RSNAT) prior authorization model to facilitate HBO model launch.
- MAC staff report no difficulty in meeting PAR turnaround times and managing PAR volume.
- MAC reviewers report spending time to help providers understand medical necessity guidelines and pre-existing documentation requirements enforced under the model in the early stages of implementation and report that providers were "learning over time."

Domain 4: Providers

Providers report increased burden, concerns about the application of medical necessity guidelines, and challenges understanding pre-existing documentation requirements enforced under the model.

- Many HBO providers report increased administrative burden under the model, difficulties in obtaining PAR supporting documentation, and delayed PAR decisions due to insufficient documents and the resulting time required for resubmission and affirmation.
- HBO providers perceive that MAC reviewers lacked the depth of clinical knowledge needed to make accurate medical necessity determinations for HBO, that medical necessity guidelines are applied inconsistently at times, and that both the guidelines and their application are too strict.
- HBO providers perceive having a significant learning curve at model launch and some continuing confusion around the pre-existing documentation requirements enforced under the model.

Domain 5: Improper payments and denied claims

At the outset of model implementation, denied claims initially rose but reverted to their pre-model level, suggesting that HBO providers were learning and becoming accustomed to the model's more strict enforcement of pre-existing documentation requirements.

- At this time, we do not report impacts on improper payments given the limitations of the Comprehensive Error Rate Testing (CERT) data.
- In the first two quarters after implementation, we observed an increase in both the number and proportion of denied claims, but the claim denial rate appears to revert to the pre-model rate by the third quarter after implementation. This pattern may reflect a learning period during which HBO providers were becoming accustomed to the more strictly enforced pre-existing documentation requirements.

Discussion, conclusions, and implications of the findings

The model decreased HBO service use and expenditures; however, the decrease on total Medicare expenditures is not statistically significant. At the same time, we have not found clear, quantitative impacts on quality of care, adverse outcomes, or access to care either across model states or for the rural and dual eligible subgroups. Since CMS selected states to participate in the

model based on their previous high use of HBO services, it is possible that a nationwide prior authorization program would achieve lower savings than observed here, as the possibility of savings in other states may not be as great as in the HBO model states.

Despite our quantitative findings indicating little clear evidence of negative effects on quality of care and adverse outcomes, some stakeholders believe that the model may result in some beneficiaries having delays in the receipt of needed treatment. These stakeholders are concerned that the model could have a negative impact on quality of care by curtailing some appropriate HBO use.

In the descriptive analysis, we observed a steep decline in HBO use in both the treatment and certain comparison states around the time the model went into effect, raising the possibility of a spillover or deterrence effect (these are described on pages 8 and 9). The presence of such effects would understate our estimates of the model's impacts on utilization, cost, and quality.

To test for the possibility of these effects, we performed additional descriptive analyses using the comparison states and states that were neither model nor comparison states. We found the decline in HBO use and costs was not uniform across states compared but did occur in some, but not all, comparison states as well as in some states that were neither model states nor comparison states. Based on these results, it appears that these effects are either not very large or not present at all.

Our study has other limitations. First, given CMS's choice of model states with particularly high rates of both historical HBO service utilization and inappropriate billing rates, the evaluation had to rely on a quasi-experimental design with comparison states rather than on the gold standard of random assignment, which limits the external validity of the findings and renders conclusions about causality less definitive. Second, most of the primary qualitative data collection for the evaluation relied on nonprobability samples of stakeholder groups (HBO providers and beneficiaries) that were recruited through an aggressive outreach effort. This sampling approach, while necessary, does not guarantee that we identified and included in the sample all types of potentially affected stakeholders in the model states. In addition, beneficiaries who participated in interviews were selected through samples of convenience and were identified and recruited with the help of HBO facility staff as part of the site visits. In these instances, stakeholders with a greater stake in model impacts or with particularly noteworthy experiences may be more likely than others to participate, and their views may not represent the experiences and perceptions of the full stakeholder population.

This page has been left blank for double-sided copying

I. INTRODUCTION

Non-emergent hyperbaric oxygen (HBO) therapy provides a therapeutic dose of oxygen by exposing a patient's entire body to pure oxygen under increased atmospheric pressure. The resulting higher oxygen concentration in the bloodstream improves wound healing (for example, from diabetic neuropathy or soft tissue damage from radiation treatment). Hyperbaric oxygen therapy takes place in a pressurized, atmosphere-controlled chamber, typically lasting 90 to 120 minutes per treatment. Depending on the condition being treated, HBO therapy is usually administered in one to two sessions a day, five days a week. The mean payment amount per individual session in 2012 for the beneficiaries in our analysis was $339.44.

Past audits of Medicare claims and medical records have revealed a high improper payment rate for HBO therapy. A 2000 report by the Department of Health and Human Services (DHHS 2000) Office of the Inspector General (OIG) found that more than 38 percent of the Medicare payments to outpatient facilities and physicians for HBO therapy was for inappropriate or excessive treatment; the OIG also raised concerns about quality of care, citing a lack of physician monitoring or appropriate testing to confirm diagnoses supporting the use of HBO. In 2006, Medicare issued a National Coverage Determination (NCD) for HBO therapy that lists 15 clinical conditions for which HBO therapy is medically necessary (either alone or as an adjunctive therapy), as well as clinical conditions for which HBO therapy is not medically necessary and, therefore, not covered by Medicare (CMS 2006).[3,4]

Model background

Prior authorization is a utilization management strategy intended to reduce improper payments by requiring that the health care payer review claims for services to assess compliance with coding, billing, and coverage rules (including medical necessity) before providers render services to beneficiaries and submit claims for payment. Thus, prior authorization is designed to contain costs and reduce waste, fraud, and abuse. Several other government and private-sector health care payers already use prior authorization practices (TRICARE 2016; AMA 2013), including Medicare Part D pharmaceutical plans (DHHS 2015). Research indicates that such programs can be effective in reducing expenditures on the service or benefit covered by the prior

[3] The NCD also includes specific guidelines regarding the use of HBO therapy to treat diabetic lower extremity wounds, which is a key focal population of the analysis. It states "The use of HBO therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care. Standard wound care in patients with diabetic wounds includes: assessment of a patient's vascular status and correction of any vascular problems in the affected limb if possible, optimization of nutritional status, optimization of glucose control, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, appropriate off-loading, and necessary treatment to resolve any infection that might be present. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment." (CMS 2006)

[4] Some states (including New Jersey) have MAC jurisdictions that operate under a local coverage determination that they develop, which may be stricter than the national coverage determinations set forth by Medicare.

authorization requirement (MacKinnon and Kumar 2001, Asher et al. 2017). A Centers for Medicare & Medicaid Services (CMS) model involving prior authorization for power mobility devices has shown a large decrease in monthly expenditures on included devices (CMS 2014). In addition, the evaluation of prior authorization for repetitive scheduled non-emergent ambulance transport (RSNAT), conducted under this contract also demonstrated large decreases in expenditures and utilization for RSNAT services (Asher et al. 2017). By ensuring a service is covered before a claim is paid, prior authorization may lower Medicare fee-for-service spending while maintaining or improving quality of care. However, there is a risk that some beneficiaries may experience denial or delay of needed care as a result of prior authorization requirements (Bergeson et al. 2013).

In April 2015, the prior authorization model for outpatient HBO therapy began in Michigan, followed by Illinois and New Jersey in August 2015; approximately 113 providers across these three states were affected. CMS selected these states based on high rates of utilization and claims error rates, and will continue the model through February 2018. Providers who fail to seek prior authorization for submitted outpatient HBO therapy claims are subject to prepayment review, which usually is reserved for a small portion of claims that stand out to reviewers because of beneficiaries' previous history or other factors. Prepayment review is designed to ensure that providers in a model state who choose not to request prior authorization are not able to evade review of their HBO claims for medical necessity and appropriate use.

The prior authorization model for HBO applies to a subset of five of the 15 conditions covered for HBO use by Medicare Part B, and reinforces existing policy that certain medical necessity criteria must be met for each of these conditions in order to be covered (Table I.1 lists the five conditions[5], and medical necessity guidelines and supporting documentation recommended by the MACs, for each). An affirmative prior authorization decision permits up to 40 courses of treatment per PAR in a 12-month time period. Beneficiaries exceeding 40 courses of treatments in a 12-month period must submit an additional PAR. While Illinois and Michigan operate under the national coverage determination set by Medicare, the MAC administering New Jersey has adopted a local coverage determination for HBO that is in some ways stricter than the national coverage determination. For example, the national coverage determination does not specify a test or test result that indicates suitability for HBO; the local coverage determination in effect in New Jersey specifies that in most cases, a beneficiary should have an ankle brachial index of no less than 0.6. Stricter requirements such as this may contribute to differential impacts for New Jersey in comparison to the other two model states.

[5] Originally, six conditions were used in the model. The condition compromised skin grafts was removed early in the model implementation period after CMS considered feedback from providers that this condition was more emergent in nature.

Table I.1. Conditions applicable to HBO prior authorization

Condition	Medical necessity guidelines	MAC-recommended documentation
Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management	HBO therapy is covered only when the condition is unresponsive to conventional medical and surgical management	Medical records should: • Support an initial diagnosis of osteomyelitis with a report of a diagnostic procedure, such as (but not limited to) CT (computed tomography), MRI (magnetic resonance imaging), or bone scan. • Identify the conventional medical management to which the patient did not respond. • Identify the conventional surgical management to which the patient did not respond. • Support that the diagnosis of chronic refractory osteomyelitis has been unresponsive to both medical and surgical management.
Osteoradionecrosis as an adjunct to conventional treatment	HBO therapy is covered only as an adjunct to conventional therapy	Medical records should: • Identify the anatomical location, the reason, and the dates the radiation treatment was received. • Support the diagnosis of osteoradionecrosis with a report of a diagnostic procedure, such as (but not limited to) X-ray CT or MRI. • Identify the conventional treatment/therapy the patient is receiving.
Soft tissue radionecrosis as an adjunct to conventional treatment	HBO therapy is covered only as an adjunct to conventional therapy	Medical records should: • Identify the anatomical location, the reason, and the dates the radiation treatment was received. • Support the diagnosis of soft tissue radionecrosis with a report of a diagnostic procedure, such as (but not limited to) visual examination, biopsy, or CT. • Identify the conventional treatment/therapy the patient is receiving.
Actinomycrosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment	HBO therapy is covered only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment	Medical records should: • Identify the location of the infection • Support the diagnosis of actinomycosis with a report of a diagnostic procedure, such as (but not limited to) results of sputum, pus, or biopsy specimen cultures. • Support the surgical incision and drainage of lesions. • Identify the prolonged administration of appropriate antibiotics. • Identify the conventional treatment/therapy the patient is receiving.

Condition	Medical necessity guidelines	MAC-recommended documentation
Diabetic wounds of the lower extremities in patients who meet the specified criteria	HBO therapy is covered only if (1) the patient has Type I or Type II diabetes and has a lower extremity wound that is due to diabetes; (2) the patient has a wound classified as Wagner grade III or higher; and (3) the patient has failed an adequate course of wound therapy as defined in the NCD	Medical records should: • Include an assessment of patient's vascular status and correction of vascular problems if possible, such as (but not limited to) ABI (ankle-brachial index), toe signals, or interventions performed by a vascular surgeon. • Support optimization of nutritional status, such as (but not limited to) lab work and dietetic teaching. • Support optimization of glucose control, such as (but not limited to) Hemoglobin A1c or serial glucose levels. • Describe debridement to remove devitalized tissue. • Identify wound care management that includes maintenance of a clean, moist bed of granulated tissue with appropriate moist dressing. • Identify appropriate off-loading. • Identify treatment to resolve any infections.

Source: CMS, NGS, and Novitas; Mathematica interviews with MAC and industry physicians.

The evaluation

This evaluation will measure the impact of the prior authorization model on the Medicare program (including the MACs), providers, and beneficiaries. The evaluation has four primary objectives:

1. Estimate the impact of prior authorization on the volume of HBO services delivered. Estimate the impact of prior authorization on Medicare expenditures and administrative burden.
2. Evaluate the effect of the model on HBO provider practices, organizational structure, and economic outcomes, including case volumes and Medicare payments. This process includes examining the level of burden that providers face in complying with prior authorization requirements.
3. Assess whether prior authorization affects beneficiaries' quality of care.
4. Enable CMS to judge the adequacy of the current model for national implementation, including identifying possible changes to criteria and procedures.

The fourth objective is critical for this prior authorization model. The evaluation will assess the feasibility and utility of expanding prior authorization nationally. Even if a model meets strict cost and quality criteria, there may be opportunities for improvement in how prior authorization is implemented. Identifying features of the model that can be altered to improve its cost effectiveness or impact on quality of patient care is an important goal of the evaluation.

Data sources and outcome measures

In this evaluation, Mathematica and its partner, Provider Resources, Inc. (PRI), employed a mixed-methods evaluation design comprising both quantitative data analysis and qualitative data collection to respond to CMS's overarching research questions and probe findings particularly valuable in understanding the full impact of prior authorization in the model states. The quantitative analysis relies primarily on Medicare claims data and other Medicare administrative

records provided by CMS. Information gathered in the first two years of the evaluation focused on the perceptions and experiences of multiple stakeholder groups (MACs, HBO providers, and beneficiaries) during the introduction of the model and the first 16 months of operation. Together, the quantitative and qualitative analyses address high-level model impacts such as changes in claims volume and cost savings, along with impacts perceived "on the ground" by those administering the model, providing HBO treatment to beneficiaries, or receiving HBO treatment.

We conducted both descriptive and multivariate analyses of key quantitative indicators for the model and comparison group states. We constructed treatment and comparison groups and performed the analysis at the beneficiary level. We examined intended outcomes, such as changes in the volume of HBO services and total HBO utilization and cost. We also examined unintended outcomes, including impacts on quality and adverse events reflected in measures such as changes in unplanned hospitalizations, amputations, and deaths.

In addition, we carried out qualitative data collection in model states to provide a 360-degree view of how key stakeholders perceive prior authorization. To better understand the implementation process and any associated challenges, we conducted telephone interviews with MAC personnel from the three MACs responsible for implementing the model and reviewing PARs. We also conducted site visits to six HBO facilities (two facilities in each of the three model states), and in-person and telephone interviews with HBO providers and beneficiaries. The sampling and recruiting strategies used for each data collection activity, along with protocols, are available in the qualitative methods chapter (pp. 15) and the report appendices.

In Table I.2, we present the research questions addressed by the evaluation and indicate whether quantitative or qualitative analysis was used to answer them.

Table I.2. Evaluation research questions and data source

Research and analysis question	Quantitative analysis	Qualitative analysis
Domain 1. Utilization and expenditures		
How does the prior authorization model affect Medicare service use and cost? Was the model cost-effective for the Medicare program?		
How does prior authorization affect		
1. Total HBO therapy service use?	X	X
2. Total payments for HBO service?	X	
3. Total payments for HBO and wound therapy service?	X	
4. Total Medicare expenditures?	X	
How did medically unnecessary HBO therapy use change?		X

Research and analysis question	Quantitative analysis	Qualitative analysis
Domain 2. Quality of care		
How does the prior authorization model affect the quality of and access to care?		
Does prior authorization affect		
1. Unplanned inpatient hospitalizations?	X	X
2. Emergency room visits?	X	X
3. Amputation of lower extremity?	X	X
4. Death?	X	X
Did beneficiaries experience a delay in services?		X
Domain 3. MAC Program operations		
How does the prior authorization model affect Medicare program operations?		
What was the impact of the model on MAC operations?		
1. How was prior authorization implemented by each MAC?		X
2. How were staff assigned to prior authorization activities selected, hired, and trained?		X
3. How long did it take prior authorization staff to process decisions?		X
4. How much of a time and cost burden does prior authorization present?		X
Domain 4. Providers		
How does the prior authorization model affect providers?		
What was the impact of the model on providers' operations? Did participants consciously change practices in response to the model and, if so, how?		
1. Were there changes in providers'		X
Management practices?		
Care provision?		
Patient admission procedures?		
Communications?		
Case volumes?		
Medicare payments?		
Overall profitability?		
Fiscal solvency?		
2. Have HBO providers received appropriate information from MACs and other sources for submitting PARs correctly?		X
3. Were patient services delayed because of approval delays?		X
4. Does prior authorization reduce HBO providers' uncertainty regarding claim approval?		X
5. Does prior authorization reduce providers' burden related to appealing denied claims?		X
Domain 5. Improper payment and claims denials		
How does the prior authorization model affect error rates for payments or claims?		
Does prior authorization affect improper payment rates?	X[6]	
Does prior authorization affect claims denial rates?	X	

[6] Improper payment will be addressed in a later report through quantitative analysis.

Research and analysis question	Quantitative analysis	Qualitative analysis
Domain 6. Scalability/implications **How feasible is expanded/national prior authorization for HBO?**		
What are the major lessons learned for improvements to the prior authorization model?	X	X
Is the set of prior authorization processes and procedures adequate to allow efficient national implementation? If not, should elements be changed before considering national implementation?		X
What external factors, circumstances, or aspects of the model might limit the model's ability to realize savings in the case of national implementation?	X	X
What would enhance the model's ability to realize savings?	X	X

This page has been left blank for double-sided copying.

II. QUANTITATIVE DATA ANALYSIS METHODS

Data and population

Our quantitative analysis used final action claims for fee-for-service (FFS) Medicare beneficiaries for dates of service from January 2012 through December 2016.[7] The treatment group consisted of beneficiaries in Illinois, Michigan, and New Jersey, the states subject to prior authorization for HBO treatment. Prior authorization started in Michigan on April 13, 2015 (quarter 14), and on August 1, 2015 (quarter 15) in Illinois and New Jersey.[8] Below we describe the comparison group we used, the population restrictions we applied, the weighting strategy we used, and the key groups of interest that we focus on in the analysis.

Comparison group. The comparison group consisted of the states in the same Medicare Administrative Contractor (MAC) jurisdictions as the treatment states. This approach was intended to capture an appropriate counterfactual policy and operational environment—if the treatment states were not subject to the prior authorization model, claims from those states would be processed the same way that claims from the comparison states were processed. In addition, because states served in the same MAC jurisdiction are likely to be geographically adjacent, they may share regional characteristics that affect health utilization, cost, and outcomes. More information on the comparison group selection is discussed in Appendix A.

Our analysis assumes that there are no spillover effects across states within MAC jurisdictions, whereby beneficiaries in the comparison states could also be affected by the prior authorization model.

If present, spillover effects could happen in one of two ways. First, claims reviewers within MAC jurisdictions serving model states might be more vigilant in their review of HBO claims in comparison states due to use of the same staff or similar procedures to those deployed in model states. For example, they could more stringently enforce the existing criteria in the comparison states than they otherwise would have in the absence of the model. Second, beneficiaries may cross state lines to receive HBO treatment. Because prior authorization is required at the facility level, beneficiaries from comparison states who travel to model states for HBO services have their treatment subject to prior authorization. In either case, the comparison group of states could be contaminated because they were influenced by the model, resulting in effect estimates biased toward zero.

Because this is an important assumption underlying the analysis, we attempted to discern the presence and severity of spillover effects in two ways. First, to assess the risk of cross-state treatment, we identified the percentage of beneficiaries who received HBO treatment outside their state of residence. We verified that less than three percent of beneficiaries receive HBO treatment outside their state of residence. Second, to explore the possibility of spillovers due to changes in operations, we used both a quantitative and a qualitative approach. We quantitatively examined patterns of HBO utilization among the Medicare population across all MAC

[7] We excluded duplicate and denied claims.

[8] We therefore have 12 or 13 pre-implementation quarters (depending on the state) and 6 or 7 intervention quarters.

jurisdictions in the country. We did not find a nationwide pattern, but we did find that in a number of MAC jurisdictions, HBO utilization in the Medicare population fell noticeably (although to varying degrees). One possible explanation for this pattern is that HBO facilities—which include a number of national, multisite organizations—may have anticipated more rigorous enforcement of existing HBO requirements, requirements which are in effect in non-model states as well, even if they are not rigorously enforced at present. These organizations may have preemptively taken a more cautious approach to HBO treatment and complied with Medicare HBO coverage requirements when they had not done so before. Relatedly, MACs that were not affected by prior authorization may have become more stringent in enforcing existing medical necessity requirements when the model went into effect. Yet another explanation is that larger, independent nationwide factors, such as the transition from ICD-9-CM to ICD-10-CM, drove the observed trends in HBO utilization and expenditures. More information on the quantitative spillover effect assessment analyses we performed is presented in Appendix B.

To supplement our quantitative approach, we conducted brief informational interviews with representatives from each of the MACs participating in the model to ascertain (1) whether staff charged with reviewing prior authorization requests were also adjudicating claims from non-model states; and (2) whether the MACs disseminated any additional information to providers in non-model states within their jurisdictions. In two of the included MACs, different staff were involved in processing prior authorization requests and claims from non-model states; in the third MAC, the same staff was used. No MACs reported disseminating additional information to providers in non-model states, although information was posted on the MAC websites, which was accessible by all providers in the jurisdiction.

Based on these results, it appears that the assumption of no spillover can be used and these effects are either not very large or not present at all.

Population restrictions for quantitative analysis. We restricted our population to beneficiaries who were a) in FFS for at least part of a given quarter, b) living in one of the included states (the model states—Illinois, Michigan, and New Jersey—or the comparison group of states that share a MAC jurisdiction with one of these states[9]), and c) were identified as having one or more of the five conditions for which treatment with HBO was included in the prior authorization model. We considered the effects of the model on beneficiaries diagnosed with one or more of the following conditions:

1. Diabetic lower extremity wounds
2. Osteomyelitis
3. Soft tissue radionecrosis
4. Osteoradionecrosis
5. Actinomycosis

[9]These comparison states are Indiana, Minnesota, Wisconsin, Pennsylvania, Maryland, Delaware, and the District of Columbia.

To ascribe a condition to a beneficiary, we required at least one inpatient claim or two outpatient claims on different days no more than 90 days apart[10] featuring a relevant diagnosis code. We obtained a set of ICD-9-CM and ICD-10-CM diagnosis codes identifying these conditions from Jurisdiction L's (Novitas Solutions) local coverage determination used in New Jersey (CMS n.d.), and supplemented them with additional codes based on internal review. We consider those beneficiaries with a claim history indicating a covered condition to have had the condition from the date of the earliest claim in the qualifying set within the study period (which we refer to as the date of diagnosis). Once diagnosed, beneficiaries remain in our sample until they die, migrate out of their state of residence, or leave FFS Medicare. More information on sample identification is in Appendix C.

Our design includes beneficiaries from the date of their diagnosis and retains them in the sample to enable us to observe any long-term health outcomes affected by access to hyperbaric oxygen therapy. The consequences of delayed or insufficient treatment of the included conditions may be immediate (such as amputation, in the case of diabetic lower extremity wounds) and/or also longer term, such as higher rates of hospitalization or death among amputees. By keeping individuals in the study unless they die, move, or leave FFS Medicare, we can observe these outcomes over time and assess whether the model increases risk of adverse outcomes in the long run.[11]

Weighting strategy. To develop the most effective comparison group possible and isolate the impact of the intervention, we sought to achieve balance between the model and comparison groups on observable characteristics such as demographics, diagnosis, and Medicaid enrollment. To ensure balance on beneficiary characteristics, we used an inverse propensity score weighting approach, which involves two steps. First, we estimated a logistic regression predicting treatment status for each beneficiary living in a model or a comparison state for each quarter of data separately for each MAC jurisdiction. The following characteristics were entered into each regression model: beneficiary age; whether the person lived in a rural area (defined by MSA); gender; race (separate indicators for black, white, Hispanic, or other); and indicators for whether the beneficiary was diagnosed with diabetic ulcers of the lower extremities, osteomyelitis, soft tissue radionecrosis, osteoradionecrosis, or actinomycosis. We used the regression output to generate predicted probabilities for each beneficiary that represented the likelihood of each to live in a state where the prior authorization model was in effect. The second stage of this process involved calculating inverse propensity score weights for each beneficiary in a comparison state (all beneficiaries in a model state are given a weight of 1). These weights were designed to balance the beneficiaries in the model and comparison states on the available demographic and health characteristics, both within each MAC jurisdiction and across jurisdictions, to establish comparability for drawing inferences about the impact of the model. More information on weighting strategy is presented in Appendix D.

[10] Relaxing the requirement that the two diagnoses occur no more than 90 days apart does not appreciably change the results.

[11] As a robustness check, we tested a model in which we include a set of dummies for number of quarters since diagnosis. Our findings did not change.

Analysis groups. We examine two beneficiary groups in this report. We examine the population of Medicare beneficiaries with any of the conditions listed above to study the impact of the model on the full population of affected beneficiaries. However, some of the condition groups may have unique treatment patterns that may distort the effects that we estimate. Because beneficiaries with diabetic leg wounds comprised over 80 percent of the individuals in our sample who receive HBO, we focus our analysis on this group to look at a large analysis group being treated for the same condition. We examined utilization, cost, quality of care, and adverse outcomes (including lower extremity amputations as a condition-specific outcome) to assess whether beneficiaries whose HBO use is subject to prior authorization experience higher rates of adverse events attributable to delayed or insufficient treatment.

We dropped the first quarter of 2012 from our analyses to allow it to serve as a historical period for identifying conditions and non-HBO treatments. Our total study population consisted of 90,312 treatment state beneficiaries (51.3 percent) and 85,803 comparison state beneficiaries (48.7 percent).[12] The length of time that we observed each beneficiary ranged from 1 to 20 quarters, with a mean duration of 7.3 quarters for treatment beneficiaries and 8.4 quarters for comparison beneficiaries, for a total of 1,294,822 beneficiary-quarters.

Analytic approach

We used a combination of descriptive and multivariate analysis to address the research questions in Chapter 1. We relied on SAS Enterprise Guide for data processing, with all regressions conducted in Stata 14.2.

Descriptive analysis

We conducted descriptive analyses (i.e., not adjusting for confounding factors) that illustrate high-level changes in utilization and expenditures. We considered the following Domain 1 measures for beneficiaries with a diabetic lower extremity wound and for beneficiaries with any included condition:

- Quarterly probability of receiving HBO services
- Average quarterly payments to providers for HBO services

Multivariate analyses

Our multivariate difference-in-differences (DID) models enable us to estimate the impact of the model by controlling statistically for observed confounding factors and net out the changes in key outcomes in the comparison states over the study period. We examined utilization, expenditures, quality of care, and adverse outcomes at the beneficiary-quarter level (Domains 1 and 2). We also estimated the model's effects on denied claims (Domain 5). For more information on outcome measure construction, please see Appendix C.

We generated weighted summary statistics of the demographic and health characteristics of beneficiaries in the treatment and comparison groups, as well as their baseline levels of the outcome measures. We also generated descriptive figures to illustrate the trends in HBO

[12]We excluded 6,175 beneficiaries who moved between states during the study period.

utilization and expenditures. See Appendix D for information on the beneficiary weights and Appendix C for methods used to create the figures.

We next used generalized DID models to estimate the impact of prior authorization on each outcome. For binary variables, we used logistic regression; for count variables, we used negative binomial regression; for continuous variables, we used ordinary least squares (OLS). We weighted observations to improve balance on observable characteristics and adjusted standard errors to account for the effects of weighting and the non-independence of observations on the same individual in several quarters. We estimated two models: one which estimated an overall effect of the prior authorization requirement, and another which estimated state-specific effects. More information on our regression methods, including robustness checks, can be found in Appendix C.

This page has been left blank for double-sided copying

III. QUALITATIVE DATA COLLECTION AND ANALYTIC METHODS

Overview

The qualitative data collection performed for this evaluation is designed to assess and summarize the self-reported perceptions and experiences of individuals most affected by HBO prior authorization (PA). It incorporates multiple data sources and methodologies to gather insights from key HBO stakeholders, including MACs responsible for administering the prior authorization model operating in the states of Illinois, Michigan, and New Jersey; HBO facility staff — including physicians, other care staff, and HBO model administrators; as well as beneficiaries or their caregivers. Data collection activities included telephone interviews with MAC personnel; in-person structured interviews with facility staff conducted as a part of site visits with HBO facilities in the model states; additional telephone interviews with the HBO facility staff and beneficiaries or their caregivers; an online survey of HBO facilities in model states; and a structured in-person interview with three CPI senior staff. Additional details related to these data collection activities can be found in Appendix E: Qualitative Data Collection and Coding.

The goal of the primary data collection is to a) inform CMS on the presence and extent of the model's effect on major stakeholders during the implementation process and b) provide insights on questions that are not answerable through quantitative analysis. Specifically, the primary data collection and analysis is designed, along with the quantitative analysis, to answer the research questions identified in Table I.2 in the Introduction (on page 5).

To address these questions, Mathematica and PRI developed a series of protocols to guide the primary data collection effort. Mathematica performed an independent quality assurance review on each of these documents, and then submitted the materials to the CMS Contracting Officer's Representative (COR) for approval. Thereafter, researchers from the Mathematica and PRI evaluation teams conducted these interviews, site visits, and an online survey. Before each data collection activity, we informed respondents that their participation was completely voluntary, they could skip questions they did not wish to answer, and no identifying information about them would be revealed in data analysis or reporting. Where relevant, the evaluation team also informed respondents that we would be recording interviews to aid in future data analysis, and obtained their permission to do so before proceeding. The specific qualitative data collection protocols we used are also included in Appendix E.[13]

[13] The online survey topline report also presents each survey question within it in Appendix F.

This page has been left blank for double-sided copying

IV. QUANTITATIVE ANALYSIS RESULTS

In this chapter, we present and discuss the quantitative research findings. We organize the chapter by research question domain. Within each domain, we first present the result from the focal group of individuals with diabetic lower extremity wounds, followed by results for the population of individuals with any condition that is included in the prior authorization model.

Domain 1: Utilization and expenditures

Aggregate descriptive analysis

In this subsection we present descriptive statistics of the HBO provider and user population. These trends provide background for understanding the potential impacts of the program. This information is followed by unadjusted descriptive analysis trends suggesting that utilization and expenditures decreased more in states where the prior authorization model was in effect than in comparison state.

Over our study period, the number of providers billing Medicare for HBO for beneficiaries in our treatment and comparison states with the included conditions increased from 267 to 321 (Table IV.1). The largest increases were in Pennsylvania, a comparison state, and New Jersey, a treatment state, although all states saw increases over the study period.

Table IV.1. Number of providers billing Medicare for HBO for beneficiaries with included conditions, 2012-2016 by state

Year	Treatment states				Comparison states						Total
	Illinois	Michigan	New Jersey	Delaware	District of Columbia	Indiana	Maryland	Minnesota	Pennsylvania	Wisconsin	
2012	47	37	35	4	2	25	13	6	76	22	267
2013	49	39	44	4	2	28	13	7	79	23	288
2014	52	40	46	4	2	31	15	7	85	24	306
2015	53	45	48	4	3	30	17	7	86	26	319
2016	50	45	45	5	4	30	20	8	88	27	321

We divided our study population into diagnosis groups based on the first of the included diagnoses observed in their claims history.[14] The majority of beneficiaries in our analytic sample (over 80 percent) have a first diagnosis of diabetes (Table IV.2). Osteomyelitis is the distantly second most common first condition; over 10 percent of the analytic sample has this diagnosis. HBO use is relatively rare, with about 5 percent of the analytic sample receiving HBO at some point. There was some variation in the likelihood of HBO utilization among the diagnosis

[14] Thirteen percent of beneficiaries included in our study population have more than one diagnosis. Of these, nearly all have only two diagnoses.

groups. Beneficiaries with a first diagnosis of soft tissue radionecrosis were most likely to receive HBO (almost 12 percent of beneficiaries did), whereas beneficiaries with a first diagnosis of actinomycosis were least likely (only 0.5 percent of these beneficiaries received HBO). However, among beneficiaries receiving any HBO, beneficiaries received similar numbers of treatments and incurred similar levels of expenditures for HBO treatments across these diagnosis group. In general, the time from the first diagnosis that appears in the claim record to the first HBO session was similar across the diagnosis groups. Beneficiaries with diabetes and with actinomycosis experienced the longest gap in time between diagnosis and first HBO treatment, with both conditions having average gaps of over 200 days. The other conditions had gaps that were roughly half as long. In all cases, though, most beneficiaries who received HBO did so within a year of their qualifying diagnosis appearing on a claim.

Table IV.2. HBO utilization by first diagnosis

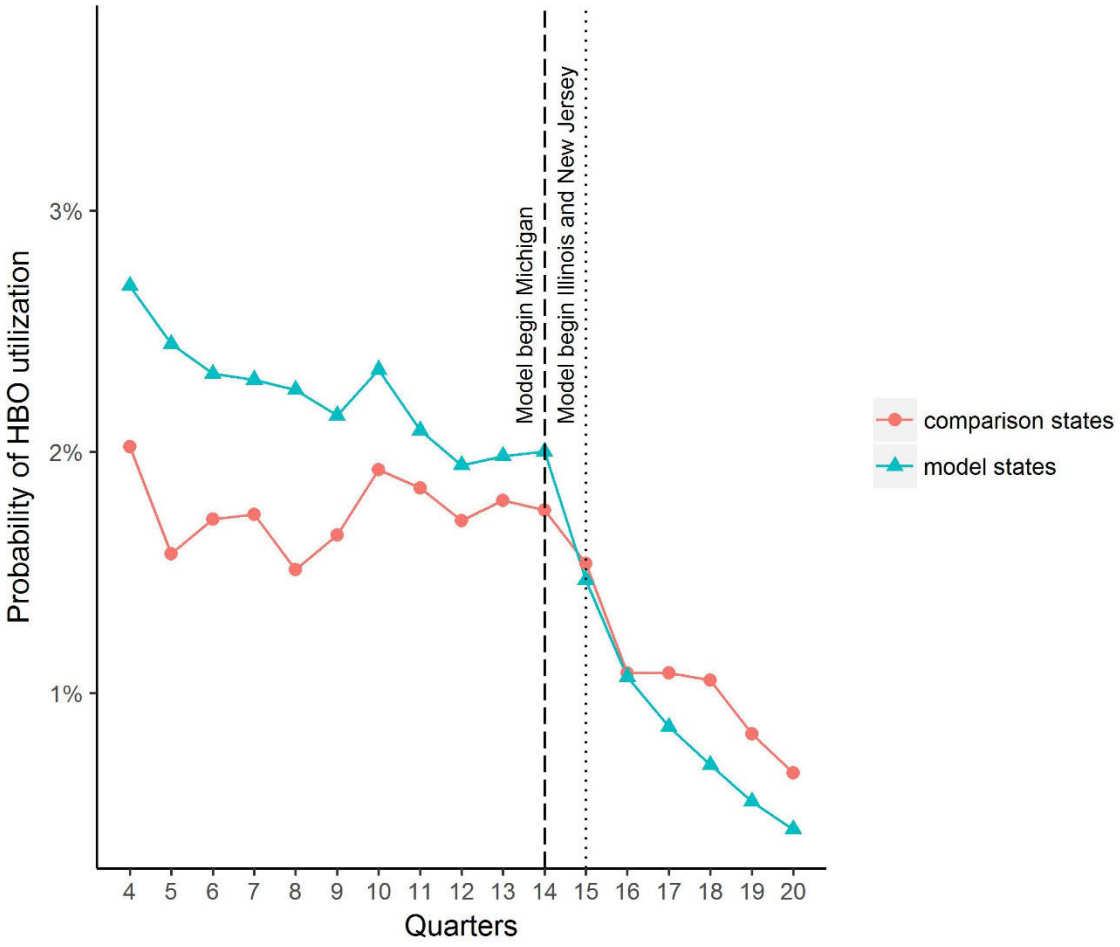
Condition	Number of beneficiaries with first diagnosis	Number (and percent) of beneficiaries with condition who ever use HBO	Average number of days of HBO treatment per user	Average HBO expenditures per user	Average annual total Medicare expenditures per user	Average annual total Medicare expenditures	Average time from diagnosis to first HBO treatment (days)
Any included condition	209,545	10,376 (4.95%)	33.97	$11,696	$208,680	$146,094	201.11
Diabetic lower extremity wound	170,496	7,443 (4.37%)	33.54	$11,445	$222,836	$147,378	232.09
Osteomyelitis	21,194	1,547 (7.29%)	35.15	$12,201	$208,777	$172,503	137.33
Soft tissue radionecrosis	9,726	1,146 (11.78%)	36.03	$12,948	$132,809	4100,586	102.75
Osteoradionecrosis	4,819	224 (4.65%)	30.24	$10,338	$125,748	$95,829	108.91
Actinomycosis	3,310	16 (0.48%)	26.88	$9,507	$209,143	$117,334	292.31

We next generated descriptive figures to illustrate how utilization and payments changed over the study period. Figures IV.1 and IV.3 present unweighted, unadjusted beneficiary-level HBO utilization and payment outcomes for beneficiaries with diabetic lower extremity wounds. In Figure IV.1, we observe an approximately 50 percent drop in utilization in the two quarters after the model begins, and a slightly more gradual continuing decrease in the following quarters. The trend appears not to have stabilized by the end of our study period. Prior to model implementation, the probability of HBO utilization was higher in model states than in comparison states. The trend lines cross during the intervention period, and the utilization rate is lower in model states after implementation. We see a similar pattern in Figure IV.2, which presents trends in utilization among beneficiaries with any condition requiring prior authorization.

We also observe a decrease in HBO utilization in the comparison group after model implementation, although it is not as large or as protracted as the drop in the treatment states. This finding may be the result of general industry trends in HBO use but could suggests the possibility of some contamination of our comparison group, perhaps due to changes in MAC operations that spill over from the treatment states to the comparison states (we noted this

possibility in Chapter II, on pages 9 and 10). Through various quantitative analyses and focused interviews (see Appendix B), we have attempted to ascertain the risk of spillovers that may affect our results. These explorations lead us to conclude that these effects are either not very large or not present at all and that our comparison group is appropriate. However, in the event that there are spillover effects, our regression models may underestimate the true impact of prior authorization.

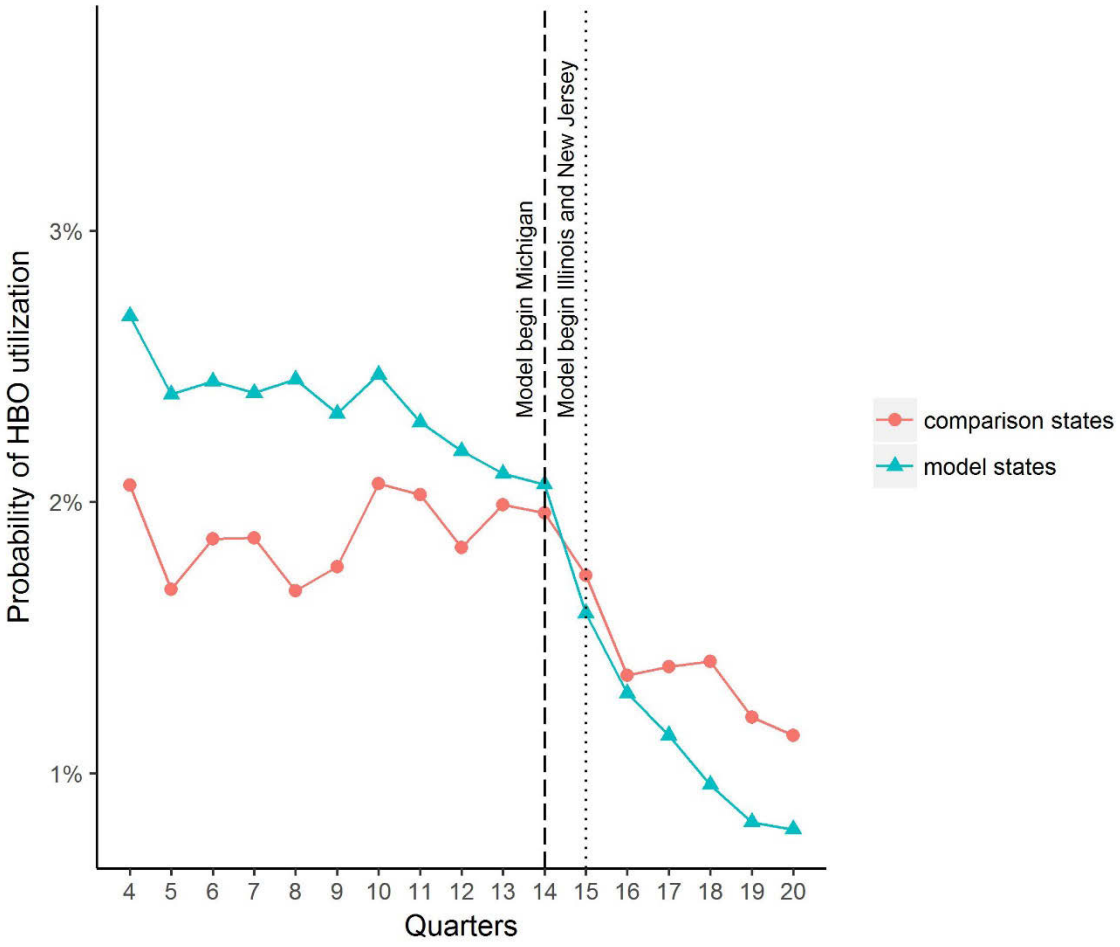
Figure IV.1. Probability of HBO utilization among beneficiaries with diabetic lower extremity wounds, by quarter



Source: Medicare FFS claims October–December 2012 (Q4) through October–December 2016 (Q20).

Note: Figure shows HBO utilization during the year following the first diagnosis of diabetic lower extremity wounds in the model and comparison states in 2012–2016. Model states are Illinois, Michigan, and New Jersey. Comparison states are Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

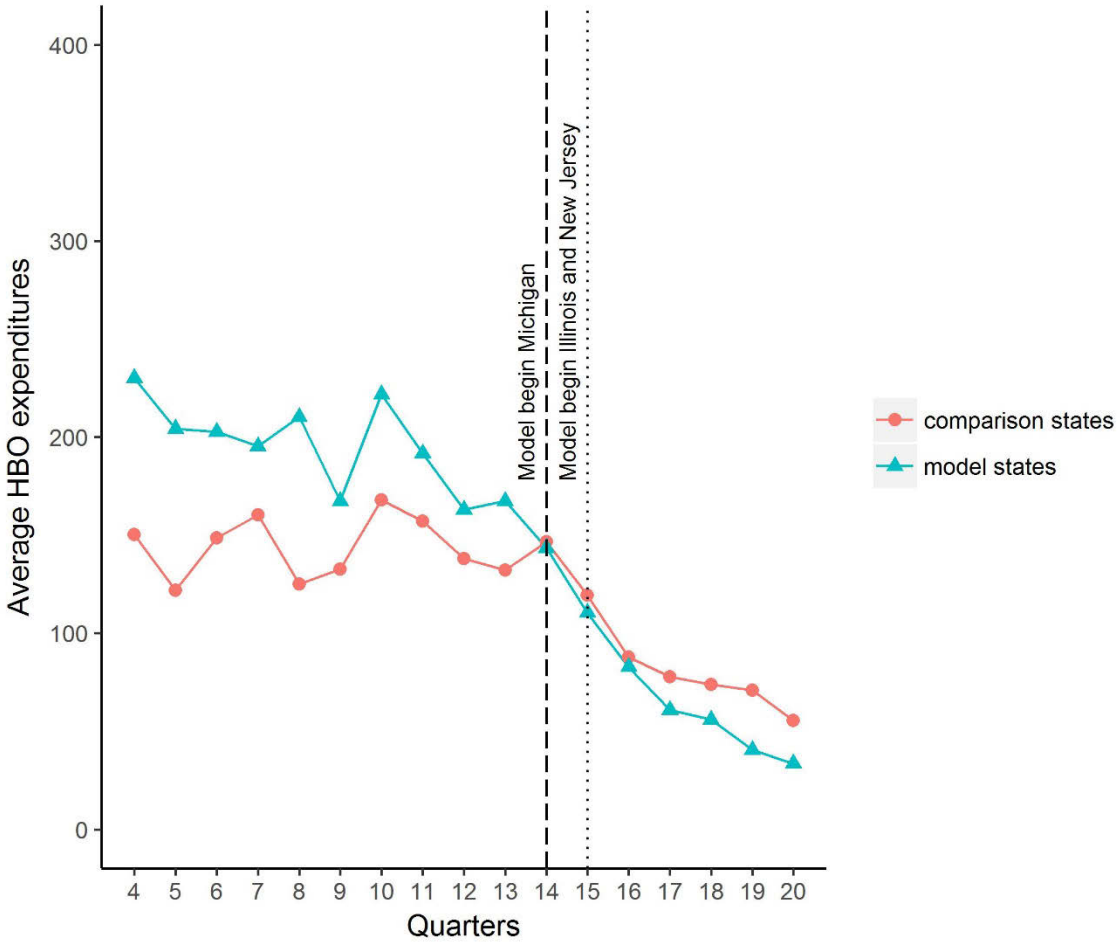
Figure IV.2. Probability of HBO utilization among beneficiaries with an included condition, by quarter



Source: Medicare FFS claims October–December 2012 (Q4) through October–December 2016 (Q20).

Note: Figure shows HBO utilization during the year following the first diagnosis of any included condition in the model and comparison states in 2012–2016. Model states are Illinois, Michigan, and New Jersey. Comparison states are Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

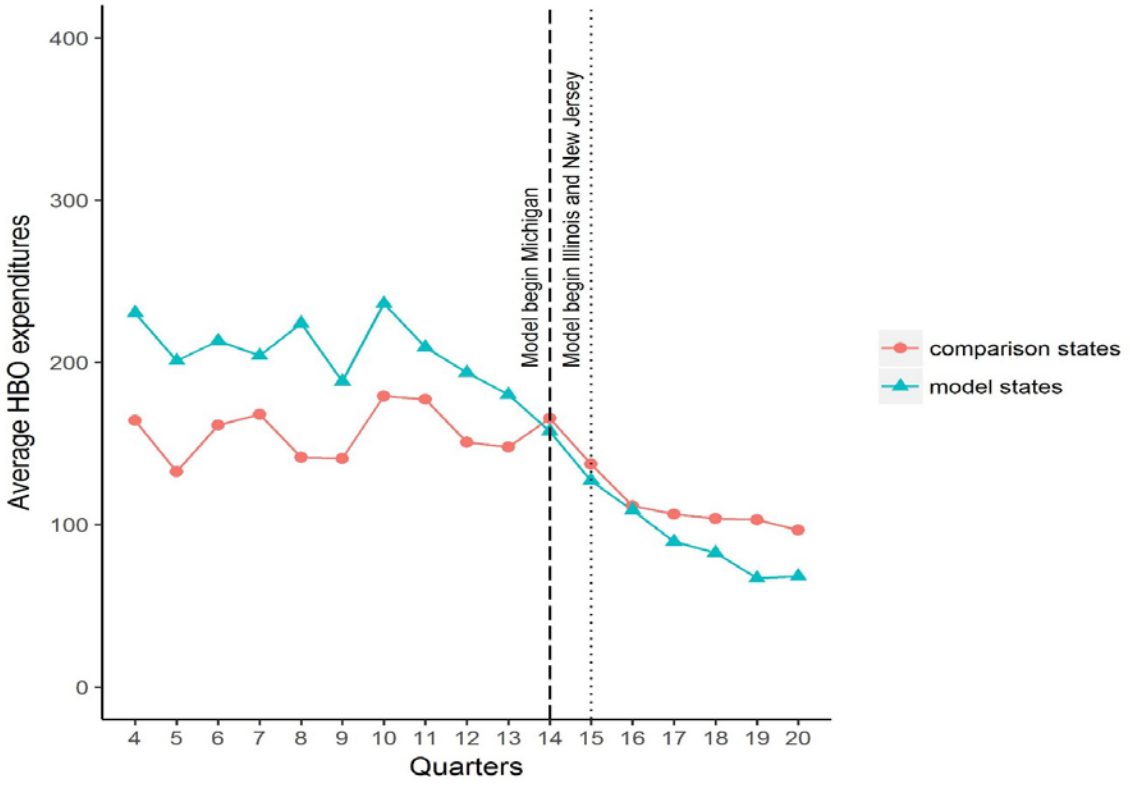
Figure IV.3. HBO expenditures per beneficiary with diabetic lower extremity wound, by quarter



Source: Medicare FFS claims October–December 2012 (Q4) through October–December 2016 (Q20).

Note: Figure shows HBO expenditures during the year following the first diagnosis of diabetic lower extremity wounds in the model and comparison states in 2012–2016. Model states are Illinois, Michigan, and New Jersey. Comparison states are Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

Figure IV.4. HBO expenditures per beneficiary with an included condition, by quarter



Source: Medicare FFS claims October–December 2012 (Q4) through October–December 2016 (Q20).

Note: Figure shows HBO expenditures during the year following the first diagnosis of any included condition in the model and comparison states in 2012–2016. Model states are Illinois, Michigan, and New Jersey. Comparison states are Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

As shown in Figure IV.3, average HBO expenditures among beneficiaries with diabetic lower extremity wounds decreased by approximately 70 percent in model states from the start of the intervention to the end of the study period in December 2016. We see a similar pattern of a decrease by approximately 60 percent in Figure IV.4, which presents trends in expenditures for HBO treatment of beneficiaries with any included condition. In the period before model implementation, average HBO expenditures were higher in model states than in comparison states. After implementation, expenditures in model states decreased relative to expenditures in comparison states, such that expenditures were higher in comparison states.

In the next subsection, we use multivariate analysis to build on these aggregate descriptive analyses examining HBO utilization and expenditures to arrive at a more complete assessment of the impacts of prior authorization on HBO utilization and expenditure at the beneficiary-quarter level. (Appendices G and H provide power calculations and describe the precision of the analyses.) We do so by including FFS beneficiaries whose claims histories indicate a condition subject to prior authorization for HBO treatment with individuals included in the sample from

the date of their first diagnosis until their death, departure from the state, or exit from FFS (see the full description in Chapter II, page 11).

Multivariate analysis

Before weighting, beneficiary demographic and health characteristics differed moderately between the model and comparison groups, but after weighting they were similar on most measures (Tables B.1a and B.1b in Appendix B). Due to CMS's selection criteria for model states, before implementation of the model, FFS beneficiaries in treatment states who met the study's condition criterion had approximately 20 percent higher quarterly utilization of and expenditures for HBO services (Tables B.2A and B.2B in Appendix B present baseline levels of utilization and expenditure).

Table IV.3 contains the primary utilization and expenditure findings of the multivariate analysis for beneficiaries with diabetic lower extremity wounds. We present the estimated average marginal effects of prior authorization for several of the key utilization and expenditure outcomes: changes in the probability of receiving HBO services, number of HBO treatments, and Medicare payments for these services. Controlling for beneficiary demographic and health characteristics, we found that among beneficiaries with diabetic lower extremity wounds, both the probability of HBO utilization and the number of HBO treatments declined. The quarterly probability that beneficiaries with diabetic lower extremity wounds received HBO services declined by 0.30 percentage points from a baseline mean of 1.87 percent (Column I, $p < 0.001$), for a 16 percent decrease. The average number of HBO treatments declined by 0.06, also for a 16 percent decrease (Column II, $p < 0.001$).

When we examined the impacts of the prior authorization requirement by state, we find that New Jersey experienced the most substantial decline in HBO utilization and number of HBO treatments among beneficiaries with diabetic lower extremity wounds. The effect of the model in New Jersey was a 0.51 percentage point reduction in the quarterly probability of HBO utilization (Column I, $p < 0.001$), or a 22 percent decrease. Illinois and Michigan experienced smaller but statistically significant decreases.

Table IV.3. Impact of prior authorization on quarterly HBO utilization and cost among beneficiaries with diabetic lower extremity wounds

	Probability of HBO utilization (percentage points) (I)	Number of HBO treatments (II)	HBO expenditures ($) (III)	Total Medicare FFS expenditures ($) (IV)
Overall impact				
Average marginal effect	-0.30***	-0.06***	-58.94***	-180.12
(standard error)	(0.05)	(0.01)	(11.07)	(215.21)
Baseline	1.87	0.37	162.77	15687.10
Change from baseline (percent)	-16.00	-16.12	-36.21	-1.15
R^2	0.05	0.01	0.003	0.06

	Probability of HBO utilization (percentage points) (I)	Number of HBO treatments (II)	HBO expenditures ($) (III)	Total Medicare FFS expenditures ($) (IV)
State-specific impact				
Average marginal effect, Illinois	-0.19**	-0.02	-15.71†	213.37
Change from baseline (percent)	-12.71	-5.94	-13.00	1.48
Average marginal effect, Michigan	-0.15*	-0.03†	-48.63***	-404.39†
Change from baseline (percent)	-8.04	-7.78	-29.37	-2.54
Average marginal effect, New Jersey	-0.51***	-0.11***	-126.44***	-314.30
Change from baseline (percent)	-21.95	-24.34	-58.82	-1.84
R^2	0.05	0.01	0.00	0.06

Note: The table presents average marginal effects and (standard errors) from weighted logistic (I), negative binomial (II), and OLS (III and IV) regression analyses using 999,030 beneficiary-quarters with diabetic lower extremity wounds for dates of service from April 2012 through December 2016. Control variables include age, age squared, sex, race, rural residence, dual eligibility for Medicare and Medicaid, and HCC score. Standard errors are clustered at the beneficiary level. Coefficients from logistic regressions have been transformed into average marginal effects. The model states are Illinois, Michigan, and New Jersey. The comparison states are Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

†$p < 0.20$, *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

We found that Medicare expenditures for HBO declined as a result of prior authorization for beneficiaries with diabetic lower extremity wounds. Average quarterly expenditures on HBO services per beneficiary with diabetic lower extremity wounds decreased by $59, for a 36 percent decrease (Column III, $p < 0.001$). Our estimate of the change in total Medicare fee-for-service expenditures was also negative, and larger than the effect on HBO and standard therapy expenditures alone. However, this change represented less than 2 percent of mean quarterly total Medicare expenditures for this analysis group and, possibly as a result, the estimated effect was not statistically significant at conventional levels overall or in any state (Column IV). Examining model state effect variation, New Jersey experienced the largest drop in expenditures on HBO services among beneficiaries with diabetic lower extremity wounds, at $126 per beneficiary per quarter (Column III, $p < 0.001$). Michigan and Illinois experienced more modest decreases.

When we analyzed utilization and expenditure outcomes for beneficiaries with any included condition, we found similar results to those observed in the diabetic leg wound group (Table IV.4). The estimated probability of HBO utilization decreased by 0.34 percentage points (an 18 percent decrease, Column I, $p < 0.001$), and the average number of HBO treatments decreased by 0.08 (Column II, $p < 0.001$), for a 22 percent decrease.

Baseline utilization rates for both beneficiaries with diabetic lower extremity wounds and beneficiaries with any condition subject to prior authorization were similar in the three states (not shown). Despite this, when we examine the impacts of the model by state, we find that New Jersey experienced substantially greater decline in HBO utilization and number of HBO treatments. The effect of the model in New Jersey was a 0.57 percentage point reduction in the quarterly probability of HBO utilization among beneficiaries with any condition subject to prior authorization (Column I, $p < 0.001$), or a 26 percent decrease. Illinois and Michigan experienced smaller, yet significant, decreases. One potential explanation for the differential impacts by state is that the MAC responsible for adjudicating claims and prior authorization requests in New Jersey (Novitas Solutions) uses a local coverage determination that is stricter than the national coverage determination used by the MACs servicing Illinois and Michigan. Another possibility is that, having implemented a previous prior authorization model for repetitive scheduled non-emergent ambulance transportation, Novitas (the New Jersey MAC) had the infrastructure and capability to implement HBO prior authorization more rapidly.[15]

Average HBO expenditures also declined by an estimated $60 per beneficiary per quarter (Column III, $p < 0.001$), a 36 percent decrease. The magnitude, significance, and percentage changes in these outcomes are similar to those estimated for the population of beneficiaries with diabetic lower extremity wounds. Also similarly, when we examined the impacts of the model across model states, New Jersey had the largest decline in HBO utilization and expenditures among beneficiaries with any condition. New Jersey experienced the largest drop in expenditures on HBO services among beneficiaries with any included condition, at $117 per beneficiary per quarter (Column III, $p < 0.001$). Michigan and Illinois experienced more modest decreases. Our estimate of the change in total Medicare fee-for-service expenditures was also negative, and larger than the effect on HBO expenditures alone. However, these expenditures represented a small fraction of mean quarterly total Medicare expenditures for this analysis group and, thus, the estimated effect was neither statistically significant overall nor in any state.

Table IV.4. Impact of prior authorization on quarterly HBO utilization and cost among beneficiaries with any included condition

	Probability of HBO utilization (percentage points) (I)	Number of HBO treatments (II)	HBO expenditures ($) (III)	Total Medicare FFS expenditures ($) (IV)
Overall impact				
Average marginal effect	-0.34***	-0.08***	-59.64***	-235.52
(standard error)	(0.05)	(0.02)	(10.29)	(192.20)
Baseline	1.89	0.38	166.76	15,054.60
Change from baseline (percent)	-17.93	-21.63	-35.76	-1.56
R^2	0.08	0.01	0.01	0.07

[15] We cannot determine with the existing data and analysis whether either of these explanations holds, or if the New Jersey MAC (Novitas) simply implemented prior authorization differently for reasons unrelated to its previous experience or its use of its local coverage determination.

	Probability of HBO utilization (percentage points) (I)	Number of HBO treatments (II)	HBO expenditures ($) (III)	Total Medicare FFS expenditures ($) (IV)
State-specific effects				
Average marginal effect, Illinois	-0.18**	-0.03†	-16.47†	136.16
Change from baseline (percent)	-10.92	-10.79	-12.51	0.97
Average marginal effect, Michigan	-0.24***	-0.06**	-54.78***	-450.48*
Change from baseline (percent)	-12.61	-15.51	-31.93	-2.97
Average marginal effect, New Jersey	-0.57***	-0.14***	-117.45***	-350.32†
Change from baseline (percent)	-25.65	-30.59	-56.64	-2.17
R^2	0.08	0.01	0.01	0.07

Note: The table presents average marginal effects and (standard errors) from weighted logistic (I), negative binomial (II), and OLS (III and IV) regression analyses using 1,220,462 beneficiary-quarters with any included condition from dates of service from April 2012 through December 2016. Control variables include age, age squared, sex, race, rural residence, dual eligibility for Medicare and Medicaid, HCC score, and a set of indicators for included medical conditions. Standard errors are clustered at the beneficiary level. Coefficients from logistic regressions have been transformed into average marginal effects. The model states are Illinois, Michigan, and New Jersey. The comparison states are Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

†$p < 0.20$, *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

We repeated our analyses, stratifying by rural residence and dual eligibility for Medicare and Medicaid among the two beneficiary groups examined. The overall results were consistent across subgroups: the effect of prior authorization on HBO utilization and expenditures was comparable in magnitude and percentage change from the baseline mean for urban and rural beneficiaries. The levels of significance were lower in the rural group, which is likely due to the smaller number of rural beneficiaries (estimated effects in urban and rural areas were not significantly different from each other). Estimated effects for non-dual eligible beneficiaries were similar in both size and percentage to those for dual eligible beneficiaries. However, the probability of HBO utilization and number of HBO treatments decreased more for non-dual eligible beneficiaries. We present the stratified results in Tables B.3a and B.3b in Appendix B.

Domain 2: Quality of care

The quantitative analysis for Domain 2 (Quality of Care) attempts to assess the impact of the HBO prior authorization model on beneficiary outcomes related to quality of care, adverse outcomes, and access to care. In order to examine the impact on quality of care, we focused on whether prior authorization affects the likelihood that HBO is delivered with physician supervision. HBO with physician supervision is considered best practice, and indeed Medicare requires that HBO be performed under physician supervision. An increase or decrease in supervision would be an indicator of increased or lowered quality in the process of care. In order to assess whether there was an increased chance of observing adverse outcomes under the model, we focused on any increases in emergency department utilization, unplanned hospital

admissions, or death. For the subset of beneficiaries with diabetic lower extremity wounds, we examined these measures but also examined emergency department utilization and unplanned hospital admissions with a primary diagnosis of a lower extremity wound, as well as amputations. Before the prior authorization model began, beneficiaries in treatment and comparison states were comparable in their levels on these measures of quality of care and adverse outcome (Tables B.4A-B and B.5A-B in Appendix B list baseline measures).

We did not find that the model was associated with decreased quality of care or increased incidence of adverse outcomes for both beneficiaries with diabetic lower extremity wounds and beneficiaries with any included condition (Table IV.5). Among beneficiaries with diabetic lower extremity wounds, the proportion of HBO treatments with physician supervision decreased slightly, but the change was not statistically significant at conventional levels (Column I, $p < 0.20$). Among participating states, the biggest decline in proportion of HBO treatments with physician supervision occurred in New Jersey and was statistically significant, which was not the case in either Illinois or Michigan. One caveat with this measure is we cannot distinguish between HBO services that were rendered without physician supervision and HBO services that occurred with supervision by limited license physicians.

Beneficiaries with diabetic lower extremity wounds are generally a group at very high risk for adverse events. Thirty-nine percent of beneficiary quarters included an emergency department visit and 31 percent experienced an unplanned hospitalization in the baseline period. We did not find that the model was associated with greater emergency department use, unplanned hospital admissions, or death for beneficiaries with diabetic lower extremity wounds. Indeed, the probability of an emergency department visit, probability of an unplanned hospitalization and probability of death each decreased significantly. The adverse outcome effects were similarly negative in direction and consistent across model states, but were statistically significant in only Michigan and New Jersey. These results should be interpreted with caution, since in most cases, the estimated effect sign is negative, which is unexpected.[16] One possible explanation for these findings might be that physicians who are unable to secure prior authorization for HBO for their patients might exert extra effort in patient monitoring and/or treating lower extremity wounds using conventional approaches. For the final report, we will explore potential additional outcome measures to test this hypothesis.

[16] HBO is not associated with large risks that might result in higher emergency department use or hospitalization. It is therefore unlikely that reducing utilization of the treatment would reduce adverse outcomes.

Table IV.5. Impact of prior authorization on quality of care and adverse outcomes among beneficiaries with diabetic lower extremity wounds

	Proportion of HBO treatments with physician supervision (I)	Probability of emergency department visit (percentage points) (II)	Number of emergency department visits (III)	Probability of unplanned hospitalization (percentage points) (IV)	Number of unplanned hospitalizations (V)	Probability of death (percentage points) (VI)
Overall impact						
Average marginal effect	-0.04†	-0.78**	-0.01†	-0.57*	0.00	-0.24*
(Standard error)	(0.03)	(0.26)	(0.01)	(0.24)	(0.00)	(0.10)
Baseline	0.92	38.71	0.68	31.10	0.45	5.32
Change from baseline (percent)	-4.64	-2.01	-1.68	-1.83	-0.74	-4.44
R^2	0.03	0.04	0.03	0.04	0.03	0.06
State-specific effects						
Average marginal effect, Illinois	-0.03	-0.30	-0.00	-0.26	-0.00	-0.13
Change from baseline (percent)	-3.29	-0.82	-0.48	-0.86	-0.35	-2.60
Average marginal effect, Michigan	-0.01	-1.03**	-0.02*	-0.66*	-0.00	-0.29*
Change from baseline (percent)	-1.56	-2.46	-2.62	-2.01	-0.31	-5.37
Average marginal effect, New Jersey	-0.15***	-1.10**	-0.01†	-0.85**	-0.01†	-0.30*
Change from baseline (percent)	-15.96	-2.93	-1.91	-2.73	-1.67	-5.30
R^2	0.04	0.04	0.03	0.04	0.03	0.06

Note: The table presents average marginal effects and standard errors from weighted logistic (II, IV, and VI), negative binomial (III and V), and OLS (I) regression analyses using 999,030 beneficiary-quarters with diabetic lower extremity wounds from dates of service from April 2012 through December 2016. Control variables include age, age squared, sex, race, rural residence, dual eligibility for Medicare and Medicaid, and HCC score. Standard errors are clustered at the beneficiary level. Coefficients from logistic regressions have been transformed into average marginal effects. The model states are Illinois, Michigan, and New Jersey. The comparison states are Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

†$p < 0.20$, *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

Among beneficiaries with any included condition, we found impacts similar to those for the diabetic lower extremity wound group (Table IV.6). The proportion of HBO treatments occurring with physician supervision declined slightly, but the change was not statistically significant at conventional levels (Column I). Among participating states, the largest decline in proportion of HBO treatments with physician supervision occurred in New Jersey and was statistically significant, which was not the case in either Illinois or Michigan. We found no evidence of an increase in emergency department utilization, unplanned hospitalization, or death for this group. Similar to the results for beneficiaries with diabetic lower extremity wounds, baseline utilization rates were high (37 percent probability of an emergency department visit and 30 percent probability of an unplanned hospitalization). We found that the probability of an emergency department visit, probability of an unplanned hospitalization and probability of death each decreased significantly. The effects for adverse outcomes were consistently negative across

states as well, but were statistically significant in only Michigan and New Jersey. Here, too, the estimated effects are unexpected and should be interpreted with caution.

Table IV.6. Impact of prior authorization on quality of care and adverse outcomes among beneficiaries with any included condition

	Proportion of HBO treatments with physician supervision (I)	Probability of emergency department visit (percentage points) (II)	Number of emergency department visits (III)	Probability of unplanned hospitalization (percentage points) (IV)	Number of unplanned hospitalizations (V)	Probability of death (percentage points) (VI)
Overall impact						
Average marginal effect	-0.03	-0.74**	-0.01†	-0.55**	0.00	-0.12†
(standard error)	(0.02)	(0.23)	(0.01)	(0.21)	(0.00)	(0.09)
Baseline	0.91	37.47	0.66	30.10	0.44	5.13
Change from baseline (percent)	-3.34	-1.97	-1.54	-1.82	-0.83	-2.34
R^2	0.03	0.04	0.03	0.04	0.03	0.07
State-specific effects						
Average marginal effect, Illinois	-0.01	-0.29	-0.00	-0.11	0.00	-0.00
Change from baseline (percent)	-1.33	-0.79	-0.25	-0.38	0.02	-0.03
Average marginal effect, Michigan	-0.01	-1.01**	-0.02*	-0.72*	-0.00	-0.17†
Change from baseline (percent)	-0.68	-2.51	-2.35	-2.27	-0.52	-3.31
Average marginal effect, New Jersey	-0.13***	-1.01**	-0.01†	-0.89**	-0.01†	-0.20†
Change from baseline (percent)	-13.78	-2.80	-2.10	-2.99	-2.14	-3.75
R^2	0.03	0.04	0.03	0.04	0.03	0.07

Note: The table presents average marginal effects and standard errors from weighted logistic (II, IV, and VI), negative binomial (III and V), and OLS (I) regression analyses using 1,220,462 beneficiary-quarters with any included condition from dates of service from April 2012 through December 2016. Control variables include age, age squared, sex, race, rural residence, dual eligibility for Medicare and Medicaid, HCC score, and a set of indicators for included medical conditions. Standard errors are clustered at the beneficiary level. Coefficients from logistic regressions have been transformed into average marginal effects. The model states are Illinois, Michigan, and New Jersey. The comparison states are Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

†$p < 0.20$, *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

One benefit of selecting beneficiaries with a diabetic lower extremity wound for separate analysis is that we can examine adverse outcome measures specific to this group. Here, we do find a small but statistically significant ($p < 0.01$) adverse effect of the model (increase) on the probability of an emergency department visit for treatment of a lower extremity wound (Table IV.7). The quarterly probability that beneficiaries had an emergency department visit for lower extremity wounds increased by 0.05 percentage points from a baseline mean of 0.51 percent (Column I, $p < 0.01$), for an 11 percent increase. Individual state effects show that, the direction and magnitude of change was similar in all states. We did not find that the model was associated with increased rates of either unplanned hospital admissions for lower extremity wounds or

amputation; indeed these effects were not significant for the total sample. For states, the probability of amputation was not significant at conventional levels.

Table IV.7. Impact of prior authorization on adverse outcomes related to diabetic lower extremity wounds

	Probability of emergency department visit for lower extremity wound (percentage points) (I)	Number of emergency department visits for lower extremity wound (II)	Probability of unplanned hospitalization for lower extremity wound (percentage points) (III)	Number of unplanned hospitalizations for lower extremity wound (IV)	Probability of amputation (percentage points) (V)
Overall results					
Average marginal effect	0.05**	0.00*	-0.01	0.00	-0.06
(standard error)	(0.02)	(0.00)	(0.02)	(0.00)	(0.06)
Baseline	0.51	0.01	0.32	0.00	2.55
Change from baseline (percent)	10.66	8.76	-2.16	-1.80	-2.2
R^2	0.03	0.03	0.01	0.01	0.01
Results by state					
Average marginal effect Illinois	0.06*	0.00†	0.01	0.00	-0.11†
Change from baseline (percent)	10.72	7.99	2.88	1.26	-4.19
Average marginal effect Michigan	0.05*	0.00†	-0.02	-0.00	0.09
Change from baseline (percent)	10.21	8.52	-6.71	-3.63	3.30
Average marginal effect New Jersey	0.05†	0.00†	-0.02	-0.00	-0.14†
Change from baseline (percent)	10.90	10.30	-4.87	-4.34	-5.93
R^2	0.03	0.03	0.01	0.01	0.01

Note: The table presents average marginal effects and standard errors from weighted logistic (I, III, and V) and negative binomial (II and IV) regression analyses using 999,030 beneficiary-quarters with diabetic lower extremity wounds from dates of service from April 2012 through December 2016. Control variables include age, age squared, sex, race, rural residence, dual eligibility for Medicare and Medicaid, and HCC score. Standard errors are clustered at the beneficiary level. Coefficients from logistic regressions have been transformed into average marginal effects. The model states are Illinois, Michigan, and New Jersey. The comparison states are Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

†$p < 0.20$, *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

In Tables B.6A and B.6B in Appendix B, we present results on quality of care and adverse outcomes among beneficiaries with any included condition and with diabetic lower extremity wounds, respectively, stratified by rural residence and by dual eligibility for Medicare and Medicaid. We do not find large differences in the estimated average marginal effects on these measures and no evidence of a decrease in quality of care or presence of adverse outcomes between rural and urban beneficiaries, or between dual-eligible and non-dual-eligible beneficiaries.

Domain 5. Improper payment and claims denials

The quantitative analysis for Domain 5 addresses the question of whether prior authorization affected claims denial rates.

In this report we do not describe outcomes related to improper payments for HBO medical procedures. The most readily available source of data describing improper payments of Medicare claims is the Comprehensive Error Rate Testing (CERT) system. CERT collects a service-level stratified random sample of claims annually to estimate the national improper payment rate for the Medicare FFS program. Although the Part B CERT samples are large, at approximately 50,000 records annually, they are not designed to support analysis for subsets of specific types of claims within a small set of states. Restricting claims to HBO-related procedures substantially decreases available sample sizes, resulting in highly unstable estimates. Thus, this analysis was not performed.

The purpose of the denied claims analysis was to determine whether prior authorization affected the extent to which claims were denied by the Medicare program. Here, we examined the proportion of submitted claims denied per beneficiary per quarter for HBO facility services.

Claim denials for HBO treatment are uncommon at the beneficiary level. Before the prior authorization model took effect, the average number of HBO claims denied was about 1 per 100 beneficiaries per quarter. Table IV.8 shows the results of the quantitative analysis using a regression model that allows for differential impacts over time. We present the average marginal effects of the model in each quarter after implementation. In the first two quarters after implementation we observed an increase in both the number and proportion of denied claims, but the claim denial rate appears to revert to the pre-model rate by the third quarter after implementation. This pattern may reflect a learning period during which providers were becoming accustomed to rigorously enforced pre-existing documentation requirements.

Table IV.8. Impact of prior authorization on quarterly beneficiary claims denials, by quarter after model implementation

	Beneficiaries with diabetic lower extremity wounds		Beneficiaries with any included condition	
	Number of denied HBO claims (I)	Proportion of HBO claims denied (II)	Number of denied HBO claims (III)	Proportion of HBO claims denied (IV)
Q1 average marginal effect	0.02**	0.09***	0.04**	0.10***
(standard error)	(0.01)	(0.02)	(0.01)	(0.02)
Change from baseline (percent)	250.43	323.99	521.22	364.74
Q2 average marginal effect	0.01†	0.16***	0.02*	0.13***
(standard error)	(0.00)	(0.03)	(0.01)	(0.02)
Change from baseline (percent)	118.09	543.72	250.15	472.34
Q3 average marginal effect	-0.00*	0.02	-0.01†	0.02
(standard error)	(0.00)	(0.02)	(0.00)	(0.02)
Change from baseline (percent)	-59.77	72.16	-66.48	59.93
Q4 average marginal effect	0.00	0.01	-0.01*	0.00
(standard error)	(0.00)	(0.02)	(0.00)	(0.02)
Change from baseline (percent)	-32.00	39.73	-80.57	8.64

	Beneficiaries with diabetic lower extremity wounds		Beneficiaries with any included condition	
	Number of denied HBO claims (I)	Proportion of HBO claims denied (II)	Number of denied HBO claims (III)	Proportion of HBO claims denied (IV)
Q5 average marginal effect	0.00	0.01	-0.01†	0.00
(standard error)	(0.00)	(0.02)	(0.00)	(0.02)
Change from baseline (percent)	-15.28	46.68	-68.35	15.4
Q6 average marginal effect	-0.01*	0.01	-0.01**	0.01
(standard error)	(0.00)	(0.02)	(0.00)	(0.02)
Change from baseline (percent)	-70.92	21.84	-104.03	22.39
R^2	0.01	0.04	0.01	0.04

Note: The table presents average marginal effects and standard errors from negative binomial (I and III) and OLS (II and IV) regression analyses using 999,030 beneficiary-quarters with diabetic lower extremity wounds and 1,220,462 beneficiary-quarters with any included condition from dates of service from April 2012 through December 2016. Control variables include age, age squared, sex, race, rural residence, dual eligibility for Medicare and Medicaid, HCC score, and a set of indicators for included medical conditions. Standard errors are clustered at the beneficiary level. Coefficients from logistic regressions have been transformed into average marginal effects. The model states are Illinois, Michigan, and New Jersey. The comparison states are Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

†$p < 0.20$, *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

V. QUALITATIVE ANALYSIS RESULTS

In this section, we present findings for each domain from the qualitative analysis, drawing on data obtained through telephone interviews with MAC personnel, site visits at six HBO facilities (two facilities in each of the three model states), in-person and telephone interviews with HBO facility staff, as well as beneficiaries and caregivers, and an online survey of HBO facilities. As described in Chapter III: Qualitative Data Collection Methods, we conducted interviews with 11 MAC personnel from the three MACs that administer prior authorization in HBO model states. During site visits to HBO facilities and in follow-up telephone calls, we conducted interviews with 30 facility staff. We also interviewed 12 beneficiaries and four caregivers of beneficiaries who are or had been patients at these HBO facilities. The online survey was fielded with 32 HBO facilities across the three model states.

Interviews, site visits, and the online survey were designed to elicit MAC staff, facility staff, and beneficiary perceptions of the effect of the prior authorization model on (1) HBO service use,[17] (2) access to and quality of care, (3) MAC program operations, and (4) HBO provider practices. In addition, the interviews and site visits were designed to elicit (5) specific ways these stakeholders felt the model could be improved.

Stakeholders' observations should be interpreted with caution since some of their perceptions may reflect the early implementation phase of the model and have become less of a concern as the model has developed. We note in the text where perceived model effects appear to be confined to or concentrated in the early implementation period. The reader also should be aware that these qualitative analyses supplement the quantitative analysis presented in Chapter IV. Finally, because interviews for this evaluation relied on convenience sampling and represent a limited number of respondents, the findings may not represent the experiences and attitudes of all MAC and HBO provider staff and beneficiaries in HBO model states. While the online survey was administered to a large sample, responses rates were low (24 percent) among facilities across model states. Complete online survey questions and results can be found in Appendix F.

[17] While we examined these questions in the qualitative data analysis described in this Chapter, this study relies primarily on the quantitative analysis to identify the effect of the model on utilization and cost.

Domain 1. Utilization and expenditures

Domain 1: Utilization and expenditures

Following the implementation of the prior authorization model:

MAC staff perceive a decrease in the number of HBO PARs submitted by providers for beneficiaries who do not meet medical necessity guidelines.

HBO provider staff at five of the six sites visited perceive that there are fewer beneficiaries being treated for HBO and that this is a result of HBO PARs being non-affirmed by the MACs.

Both MAC and HBO facility staff describe improvement in the quality of the documentation for submitted HBO PARs. Many HBO provider staff believe this improvement is due to the education and guidance they received from MAC PAR reviewers.

Overall model effectiveness in reducing medically unnecessary HBO use

MAC staff interviewed believed that implementation of the prior authorization model for HBO services has been efficient and highly effective. Overall, they report that the number of HBO PARs submitted by providers for beneficiaries who do not meet medical necessity guidelines has decreased since model implementation, and that the number of HBO PARs submitted by providers with insufficient or imprecise documentation has also decreased. MAC staff interviewed consistently reported an improvement in the quality of the documentation for all submitted PARs, as providers developed a better understanding of the medical necessity guidelines and documentation required to affirm a PAR.

In interviews, MAC personnel noted that the HBO prior authorization model applies guidelines that were already in place prior to the implementation of the model, but had not been closely monitored or enforced, rather than implement a new program or new requirements. Some MAC personnel also perceived that while HBO services had been overused before the model, only a small portion of overuse was the result of fraudulent behavior on the part of HBO providers. Rather, multiple MAC staff noted in interviews that confusion about which conditions were covered and what the medical necessity requirements were seemed to be the main driver of past HBO overutilization. They believed that HBO providers submitted claims for patients with conditions they thought were either covered or should be covered, but were not, or for patients that did not meet medical necessity guidelines. At five of the six facilities visited, HBO staff perceive that, due to an increase in the extent of non-affirmed PARs, the number of beneficiaries treated at their facilities declined after model implementation. This was particularly true at New Jersey facilities, where staff at one site reported a 75 percent decline in the number of Medicare beneficiaries treated. This may be partly due to the use of a local coverage determination (LCD) by New Jersey, rather than the national coverage determination (NCD) used by Illinois and Michigan. MAC staff noted that the LCD is more specific and detailed than the NCD, as it "gives more information where the NCD is more vague." One HBO staff person attributed the decline in New Jersey to MACs becoming "… more strict in who they are approving." Providers from the two Illinois facilities reported fewer non-affirmed PARs than the New Jersey sites, and moderate or no decline in HBO utilization rates among their patients. Providers at both Michigan facilities perceived some decline in the number of Medicare beneficiaries treated at their facility

following model implementation, but also believed that patients who they perceive as truly needing HBO treatment eventually are affirmed.

Findings from the online survey administered to HBO facilities in model states from July 18, 2017 to September 18, 2017 reflect respondent perceptions that the number of beneficiaries receiving HBO treatment has declined. Among facilities who participated in the online survey, 19 (59 percent) reported that their overall case load decreased since prior authorization was implemented. Seventy-eight percent of facilities reported that they have received at least some non-affirmed requests because their patients did not meet medical necessity criteria for a given condition. Respondents self-reported that, on average, 58 percent of their prior authorizations were affirmed after initial submission and 20 percent were affirmed after one or more resubmissions, which may be evident of improved guidance and documentation. Detailed online survey results can be found in Appendix F.

Domain 2. Quality of care

Domain 2: Quality of care

HBO facility staff state that there were delays in treatment for some beneficiaries who meet medical necessity requirements for HBO. They attributed this delay to initial non-affirmation of PARs for lack of documentation and the resulting time required for resubmission and approval.

HBO providers feel that these delays can significantly affect quality of care. They noted that for some conditions, delays in receiving HBO can result in tissue loss or other adverse outcomes.

MAC personnel believe the prior authorization model should not impact the quality or timeliness of care for beneficiaries. They cite the chronic nature of the conditions treated, their timely processing of PARs, and the ability of providers to submit PARs after HBO treatment has begun.

MAC personnel noted that beneficiaries may perceive decreased access to HBO treatment if they previously had been receiving treatment for conditions that were not eligible for payment under existing medical necessity guidelines. Under the prior authorization model, MACs now strictly enforce these existing medical necessity guidelines.

Delayed access to care

HBO providers' main concern following implementation of the prior authorization model for HBO is that, in their experience, access to HBO treatment is delayed for some beneficiaries due to what they perceive as stringent review of pre-existing documentation requirements enforced under the model. These comments were consistent across all three model states. As one HBO provider explained, for their facility, the number of beneficiaries who were non-affirmed for HBO therapy because they are deemed medically ineligible was perceived to be small. However, they noted that the number of beneficiaries whose

> "Those patients I think who are clearly identified as people who may benefit oftentimes have delayed therapy. Some patients who I think in the past may have been helped by it are now being excluded. That particular population is small. The population where the people are having some delay, then eventually get it that is becoming a large number." – HBO physician

PARs were non-affirmed initially and then affirmed later was growing. Other HBO facility staff agreed with this perception, and noted that while they generally support implementation of the prior authorization model, they believe some patients may experience delayed care.

Among facilities that responded to the online survey, 87.5 percent of HBO facilities surveyed reported that patients have delayed or cancelled scheduled HBO treatments because they were not yet affirmed for HBO therapy under prior authorization. Table 5.1 shows the conditions that patients who experienced delayed care were often being treated for, with the majority of facilities reporting diabetic wounds of lower extremities and chronic refractory osteomyelitis as the top conditions for which patients sought HBO treatment at their facilities.

Table V.1. Online survey question asks "Thinking about your patients who have delayed or canceled scheduled HBO treatments because they were not affirmed for HBO therapy, which of the following conditions were they being treated for?" [Select all that apply]

	HBO Treatment Facilities n = 28
Compromised skin grafts[18]	8
Chronic refractory osteomyelitis	18
Osteoradionecrosis	9
Soft Tissue radionecrosis	12
Actinomycrosis	0
Diabetic wounds of the lower extremities	27

HBO providers report that PARs for beneficiaries who experience a delay in care are typically non-affirmed pending submission of additional tests and medical records, or clarification of previously submitted documentation. In cases in which a beneficiary's PAR is later affirmed after initially being non-affirmed due to missing or incomplete documentation, providers note that they typically do not start treatment until authorization occurs and the resulting delay in providing HBO therapy may have a negative impact on the patient's condition. Some instances of delay reflect a learning curve experienced by HBO providers, as they become familiar with the documentation required to establish medical necessity for the five conditions covered under the model. Some HBO providers noted that they became more proficient with the PAR submission process over time and had their affirmation rate increase, leading to patients experiencing fewer delays as a result.

> "We believe in the [prior authorization] process. If anything, just expediting the process for the patients that really need to get in quickly is really all that we would request. But I think that we agree that it [prior authorization] makes sense." – HBO facility staff.

[18] As we noted earlier, compromised skin grafts was originally included in the model but subsequently removed. At the time the online survey was developed, it was one of the model's conditions available for prior authorization.

MAC staff interviewed indicate they process PARs within the designated timeframe and often try to process PARs even more quickly to limit instances where HBO providers might withhold treatment while waiting for affirmation. Further, MAC personnel cite several reasons why the prior authorization model should not be affecting the quality or timeliness of care for beneficiaries. First, the conditions covered under HBO are non-emergent. They are chronic conditions for which beneficiaries have been treated before they required HBO treatment, and HBO providers already know the treatment options available to the beneficiary as the chronic condition progresses. Other types of standard treatment can be provided while awaiting a PAR determination, which one provider also noted when interviewed.

Second, MAC staff instruct providers not to delay the provision of HBO services if they are needed. MACs can and do accept PARs submitted after the start of HBO treatment. However, some HBO providers stated that they do not provide services prior to PAR affirmation out of fear that the PAR may not be affirmed and they would not receive payment for care that is expensive for them to provide. In cases where limb loss is a major concern, 28 percent of HBO providers surveyed indicated that they have provided HBO to patients and were prepared to absorb the financial loss if the PAR was not subsequently affirmed. In many of these cases, providers stated that they did so with awareness that the patients are unable to pay for the service out of pocket and do not bill them for the service. Our quantitative analysis, reported in Chapter IV, did not find negative impacts of the model on quality of care or adverse events.

Ineligible conditions

MAC staff pointed out that beneficiaries may experience decreased access to HBO treatment if they previously had been receiving treatment for conditions that do not meet medical necessity guidelines. Enforcement of existing guidelines through the prior authorization model means that providers are no longer able to receive payment for providing HBO for conditions that do not meet eligibility requirements. HBO providers we interviewed cited multiple conditions or circumstances for which they would prefer to provide HBO therapy but for which the patient is ineligible or for which PAR affirmations are now more difficult to obtain. These included:

- Beneficiaries who have recurring wounds over a long period of time but do not have an underlying condition that is eligible for HBO. HBO providers may believe HBO treatment can improve patients' wound healing, but if it is ordered, it will not be covered by Medicare.
- Beneficiaries who are receiving other treatment and who HBO providers feel may benefit from HBO as a complementary and co-occurring treatment. Providers feel that the time needed to obtain affirmation often serves as a barrier to providing both types of treatment concurrently.
- Beneficiaries with osteoradionecrosis of the jaw, which is difficult to adequately document and for which HBO is one of very few treatment options. (HBO was also mentioned as a gateway to other treatments by these providers.)
- Diabetic patients with wounds for which it is difficult to show that adequate debridement has been done.

Some HBO providers also indicate that in cases where alternatives to HBO therapy are available or the patient does not meet medical necessity requirements for HBO therapy prior

authorization, HBO may be perceived by these providers as the *preferable* course of treatment because it promotes faster, longer lasting healing, is less intrusive than other treatments, and may reduce the risk of later infection. According to one HBO provider interviewed:

> "Yes, I think it [the prior authorization model] is significantly affecting the outcomes. It's delaying the care that they need in a timely manner. And affecting the quality of life absolutely, because in my diabetic patients who have hyperbaric, the wound that heals with hyperbaric, they can get other wounds on their leg, but that wound you will never even know it was there. It heals so beautifully, whereas in others you can heal them and five months later they are back with the same wound, because that tissue is not strong enough." - HBO physician

Beneficiary experiences

The beneficiaries and caregivers we interviewed typically report being referred to HBO by other practitioners, including dentists, primary care physicians, oncologists, and podiatrists. Following referral, their experiences varied. Some beneficiaries reported waiting just a day from the submission of the PAR by their provider to the scheduling of their HBO sessions, while others were still waiting for an affirmation at the time of their interview, several months after the initial PAR submission. Several beneficiaries questioned the economic benefit of prior authorization, reasoning that the costs associated with wound care, amputations, and physical therapy seemed comparable to that of HBO, for what they perceived to be less effective care and to result in less desirable outcomes.[19]

Findings were mixed on how much beneficiaries knew about and understood medical necessity requirements and the prior authorization process. All beneficiaries interviewed reported having some level of understanding of HBO therapy itself, with most noting the ability of HBO to promote healing and increase blood flow through the provision of oxygen, and others highlighting the role that HBO can play in enhancing blood vessel and bone growth. While beneficiaries generally seemed far removed from the PAR submission and decision process, many noted that they were frequently updated on the status of their submission by their HBO provider.

Most beneficiaries who were receiving HBO therapy reported few side effects, little or no stress or anxiety related to getting the treatment, and no financial burden or stress about the costs associated with HBO once they received affirmation and were not financially liable for the care. Most reported knowing that HBO is expensive and said that they would not be able to bear the cost themselves and would bypass this treatment option altogether if deemed ineligible. Patients who received HBO expressed happiness and satisfaction in getting back or retaining their independence, reporting that HBO helped them to heal, remain active, and in one case, continue working.

Few beneficiaries reported adverse health impacts while waiting for prior authorization for HBO treatment. Some reported visits to other providers to treat their condition while they waited

[19] During site visits in New Jersey, we interviewed a significant number of beneficiaries and caregivers who were waiting for HBO prior authorization approval, compared to the other model states, where many of the beneficiaries had already begun HBO treatment.

for their PAR decision and mentioned their concerns about the out of pocket expenses they incurred for these visits. Several beneficiaries also noted that they feared amputation, infection, and death as a result of not receiving HBO treatment, and that the waiting period for a PAR decision can be stressful for them. Some of the older patients interviewed also noted that they viewed HBO as a potential means of improving their quality of life in their later years, making access to HBO even more important to them personally. Several caregivers of patients waiting for HBO treatment reported stress from caring for their loved ones and a fear that lack of access to HBO could result in them having to care for their loved ones long-term, which could impact their jobs and families.

Among the 32 facilities that responded to the online survey, 56.3 percent of HBO facilities noted that prior authorization has resulted in some beneficiaries who are not affirmed for HBO relying on emergency care to treat their condition, while 81.3 percent perceived that some beneficiaries are experiencing adverse health outcomes as a result of not being affirmed for HBO therapy. In contrast, our quantitative analysis, reported in Chapter IV, did not find negative impacts of the model on quality of care or adverse events in the rate of emergency room use and hospitalizations relative to prior to the model start when compared to similar time points in the comparison states.

Domain 3. MAC program operations

Domain 3: MAC program operations

MAC personnel stated that they can meet the mandated timeframes for making PAR determinations.

Both MAC personnel and HBO providers note that MAC education and outreach to providers is critical to a successful prior authorization model implementation.

In interviews, MAC staff generally viewed the prior authorization process as working efficiently and effectively, and indicated the model has been successful in limiting HBO treatment to beneficiaries who meet medical necessary guidelines.

Operationally, MAC staff we interviewed reported no problems keeping up with the volume of PAR requests or reviewing PARs within the required timeframe. Novitas (the MAC for New Jersey) is also participating in the Repetitive Scheduled Non-emergent Ambulance Transportation (RSNAT) prior authorization model, launched in December 2014. Interviewees at this MAC report that they were well-positioned to implement the HBO model by adapting the systems and processes developed for the RSNAT prior authorization model. For example, they reported modifying the prior authorization tracking system set up for the RSNAT model to enable them to implement the HBO model efficiently. While implementation of the HBO model required the

> "As far as reducing unnecessary services or fraudulent claims, prior authorization is working very well since we're reviewing 100% for those particular medical conditions. We haven't seen anything that's fraudulent, however we've seen a lot of [things that are unnecessary or outside of the medical necessity]. We've prevented that billing where providers have been billing and getting paid for that in the past." —MAC staff

other two participating MACs to develop new systems and procedures to process prior authorization requests, they too reported successful and effective model launches.

Prior authorization implementation

Similar to the RSNAT prior authorization model, MAC staff report utilizing a tiered review process for the HBO model in which PARs are first assessed for technical completeness (completed forms, required signatures, correct dates, etc.), and only then are reviewed for medical necessity. If technical issues are found, a PAR is returned to the submitting provider or a MAC may telephone providers to let them know the PAR cannot be processed because of missing or incomplete information. If a PAR is not affirmed for either technical or medical necessity reasons, the MAC drafts a decision letter to the provider, listing each reason for the decision. Typically, there is more than one reason that a PAR is not affirmed and non-affirmation reasons can differ for the five conditions subject to HBO prior authorization, according to those we interviewed. Not surprising, MAC staff report that the most common reason for non-affirmed decisions is that the beneficiary's condition is not eligible for treatment under the medical necessity guidelines.

Education and training

The MACs report providing internal training to their staff who review HBO PARs. They also report providing education and support about the prior authorization model to HBO providers. Internal training for MAC staff includes education on the medical necessity guidelines for each of the five subject conditions, to ensure MAC reviewers interpret the guidelines accurately and consistently. In addition, internal staff receive training on the MAC's systems and processes for reviewing PARs. MAC staff report having developed supplemental resources to help facilitate reviews, such as submission checklists, medical documentation checklists, and letter templates for notifying providers of their decisions. Further, MAC staff describe an open-door policy with supervisory and management staff that enables line-level reviewers to feel comfortable clarifying the process and guidelines with senior-level staff.

The MAC staff and HBO facility staff agreed that education and outreach to HBO providers is a critical part of the prior authorization process. MAC staff described resources developed specifically for HBO providers, such as checklists for each condition covered under the HBO prior authorization model. In addition to these checklists, HBO facility staff indicated that MACs have posted resources to their websites, including links to the national coverage determination (NCD) and in New Jersey, the local coverage determination (LCD) for HBO therapy, frequently asked questions, and a fax cover sheet template with submission instructions. In the online survey, among HBO facilities that reported contacting MACs for clarification or assistance, 68 percent reported that their MAC was helpful.

MACs further report hosting webinars for HBO providers and posting information about the model received from CMS to their websites. In addition to these formal resources, MAC staff noted in interviews that they give individual support to HBO providers as needed. Open communication with providers was a common theme among interviewees. According to one

> "…The submissions are getting better and more direct to try to meet medical criteria for HBO therapy and the conditions and what needs to be shown under each condition."—MAC staff

MAC staff member, if a reviewer notices a trend in errors or missing information on PARs, that reviewer will reach out to the HBO provider to engage in a discussion and help the provider identify the issues causing the errors. Further, if a provider disagrees with a decision and would like to discuss it with a MAC physician, MAC staff noted that they allow the provider to speak to a medical director at the MAC to review the interpretation of guidelines.

MAC staff noted general improvement over the initial months of the model in the quality of PAR submissions by HBO providers. MAC staff attributed much of this improvement to their education and outreach efforts to providers during the initial implementation phase. During early implementation, it was not uncommon for MACs to review PARs that were between 500 and 1,500 pages in length, according to one MAC interviewee. The average submission has now decreased to between 30 and 50 pages. Interviewees noted that some of this early confusion was due to a lack of pre-model education for some HBO providers.

Processing reviews and decisions

Throughout the interviews, MAC staff stated that they had not encountered difficulty with the mandated timeframes for reviewing and making determinations on submitted PARs. MACs are required to review a PAR within 10 business days of receiving the initial request. MACs also are required to review *expedited* requests within two business days of receiving the request. MAC staff reported that they often make an affirmation decision well within the allotted 10-day timeframe. For example, one staff member noted they achieve an average turnaround time of about five business days.

MAC staff noted that expedited requests are more challenging to meet in the required two-day timeframe, but they prioritize expedited PARs for review when they receive them. One interviewee reported that while the MAC receives a number of expedited requests, it does not accept all of them; most are processed as standard requests within the normal 10-day timeframe. Expedited requests are only reviewed immediately in instances where the standard 10-day review timeframe could jeopardize the life or health of the beneficiary.

Medical necessity guidelines

Establishing medical necessity is the core component of PAR determinations. The medical necessity guidelines for HBO therapy are provided in the NCD manual, limiting Medicare reimbursement for HBO therapy to 15 conditions. As noted earlier in this report, prior authorization applies to five of those 15 conditions and each condition has unique medical necessity requirements. New Jersey MAC staff noted that their LCD is more comprehensive than the NCD, as it contains more detailed information and clarification where the NCD is less detailed, but the same conditions are covered and the same requirements apply in both. MAC staff report that lack of medical necessity is the main reason HBO PARs are not affirmed. From the perspective of MAC staff, the medical necessity guidelines are clear. However, because these requirements for HBO therapy coverage were not always strictly enforced prior to model implementation, HBO providers are not entirely familiar with them and often learn about them after model implementation as they submit PARs. MAC staff also recognize that disagreement exists between them and HBO providers on the clarity, application, and appropriateness of the medical necessity guidelines for determining a beneficiary's eligibility for HBO services (discussed in Domain 4 findings).

It is important to note that while HBO providers have access to the NCD or LCD manuals, MAC staff point out that these manuals do not list all of the diagnostic codes covered under the HBO model and therefore HBO providers do not have access to the full list. This creates confusion for HBO providers. By developing educational resources, MAC staff believe that they have helped to clarify medical necessity guidelines for providers.

> "We've seen a lot of miscoding whenever they're doing HBO. What I have now educated the facilities to do is don't look at the codes because the codes are only there for billing, because that's what they've been using for medical necessity. What I've found is that the majority of facilities are getting the diagnosis code and saying, okay, they meet medical necessity because this diagnosis code fits them. Well, the thing is, is that [the] diagnosis code[s], they have a broader spectrum than what the medical condition that's covered does."—MAC staff

Domain 4. Providers

Domain 4: HBO Providers

Many HBO providers interviewed express concern about the administrative burden of the model and difficulties obtaining supporting documentation.

Many HBO providers feel MAC reviewers do not have the depth of clinical knowledge necessary to make medical necessity determinations for HBO, that the guidelines are applied inconsistently at times, and that both the guidelines and their application are too strict.

HBO providers report experiencing a learning curve at model launch as well as some continued confusion around pre-existing requirements enforced under the model; they suggest additional provider education would be beneficial.

In site visits and interviews, HBO providers reported several concerns with the prior authorization model including its impact on facility staff, questions about the appropriateness and application of medical necessity requirements by MAC reviewers, and the need for more provider education prior to and during model implementation.

Administrative burden and documentation requirements

Many HBO providers expressed concern about the burden placed upon them and their staff by the prior authorization model, resulting from the need to obtain appropriate documentation for PAR submissions, review MAC feedback, conduct additional medical tests and procedures, obtain needed supporting documentation from outside sources, and resubmit materials for additional review as necessary. Some HBO providers reason that the prior authorization process takes up time and resources that could otherwise be allocated to clinical care, and feel that the prior authorization process reduces their administrative efficiency. Some HBO providers acknowledge, however, that because these requirements were already in place, there should be little change or disruption as a result of model implementation. Among survey respondents, 93.8 percent of facilities reported that HBO prior authorization has increased time spent on administrative duties by staff.

HBO providers also consistently expressed concern about what they perceive as unnecessarily long PAR turnaround times that result in delayed care for some patients. Many

point to repeated requests for additional information for a particular PAR from MACs as a main contributing factor in delaying PAR decisions. As noted earlier, MACs employ a two-tiered PAR review process in which PARs are first reviewed for technical completeness and then reviewed for medical necessity eligibility. The HBO providers interviewed feel the two-tier review process is inefficient, not only because it results in multiple requests for additional information for the same PAR, but because providers are often contacted by different MAC reviewers with each new request. In addition, HBO providers report that feedback from MAC reviewers on submitted PARs is often inconsistent, with different reviewers requesting different documentation and clarification.

To address these concerns, HBO providers we interviewed suggest that MACs should conduct one thorough review, identifying all of the missing pieces before requesting more information, and that the same reviewer should evaluate the initial submission and any subsequent resubmissions on a specific PAR. They feel this reviewer would be in the best position to review newly submitted documentation and that communicating with one reviewer on each PAR would be more efficient for both the MACs and HBO providers.

At the same time, despite these concerns, HBO providers typically report that HBO facility staffing has not been directly affected by the model's implementation, and that their organization has been able to rely on current staff to manage the PAR submission process and avoid making additional hires. In one case, an HBO nurse noted that the model has played a role in limiting the risk that HBO management companies face for claims that might not be paid upon review. With an affirmed PAR, providers know that HBO claims for Medicare patients will likely be paid.

> "It pulls me away from doing clinical care, because I have to make sure that it's accurate or they'll deny. So I'm not only running the unit, but I'm also counted as a nurse to take care of patients who come and go in the clinic. So I have to find time to do all that stuff." – HBO provider

In interviews, HBO providers describe playing various roles in the administrative tasks that are part of HBO prior authorization at their facilities. All staff interviewed described PAR submission as a team process, in which everyone plays an important role in gathering documentation, submitting materials, and following up when necessary. HBO providers consistently reported challenges collecting medical necessity documentation and working back and forth with clinicians who are providing supporting information for a beneficiary's PAR. HBO staff we interviewed who are not directly involved in the PAR submission process note they are aware of the impact of the model because they perceive that it is taking more time to get patients into HBO therapy than was the case prior to model implementation.

Appropriateness and application of medical necessity guidelines

Many HBO providers we interviewed expressed concerns about both 1) the appropriateness of the medical necessity guidelines for the five conditions subject to prior authorization and 2) the application of guidelines to specific cases. The appropriateness of medical necessity guidelines was questioned by HBO providers who disagree with the clinical criteria used. These concerns reflect broader clinical and policy debates among and between HBO providers and payers, and are not addressed in this report.

The other common concern expressed by HBO providers—that, in their view, medical necessity guidelines are not applied correctly in all cases—reflects specific aspects of model implementation and performance that are relevant to this evaluation. Among the concerns expressed by HBO providers about the application of medical necessity guidelines are the following:

- HBO providers see the review process as, at times, too rigid and methodical, with requests for resubmissions calling for what they feel are unnecessary medical procedures and testing to meet checklist and paperwork requirements. Some view that the process does not allow enough flexibility to consider beneficiary needs on a case-by-case basis. Similarly, several physicians expressed concern that the prior authorization model limits their ability to use their professional judgment due to the use of checklists and what they perceive as rigid criteria in the PAR submission and review process.
- Several HBO providers interviewed reported dissatisfaction with peer-to-peer reviews in which HBO physicians discuss with MAC physicians prior authorization determinations they disagree with or have questions about. Some providers reported feeling that MAC reviewers are not always knowledgeable enough on the subject matter, do not specialize in HBO therapy, or cannot always be reached in a timely manner due to conflicting schedules. Further, while HBO providers have found peer-to-peer discussions helpful in obtaining affirmed PARs in some cases where clarification was needed, HBO staff and treating physicians report that this process is not sustainable for them for every non-approved case.
- A few HBO providers in New Jersey reported perceived inconsistencies between PARs that were previously affirmed early in the model and similar requests that are now non-affirmed later in the model. They cite situations in which patients and conditions seem similar, but feel they are having a more difficult time getting the PAR affirmed now than before. As a result, some of these HBO providers who were interviewed wondered if requirements and guidelines have changed since model implementation and they have not been kept adequately informed. Some HBO providers also express continued confusion about the conditions covered under the model and the medical necessity requirements for those conditions.

Education and awareness

By and large, staff and physicians interviewed from HBO facilities reported learning about the prior authorization model through their facility leadership, internal managers, and CMS. Many reported first hearing about the prior authorization model after it already went into effect. HBO providers noted that education on the PAR submission process and requirements is often provided on an ad hoc basis as they submit PARs, with reviewers providing feedback on what is missing from each submission. To some HBO providers, this feels like a trial and error process, and some report that they still do not have a good understanding of the documentation required to have a PAR affirmed.

Providers also commonly report that in addition to learning pre-existing model requirements and processes during the submission process, the guidance they receive from MACs is at times insufficient and sometimes inconsistent across MAC reviewers. While many HBO providers feel the feedback and materials provided by MACs have been helpful in most cases, they also suggest

that MAC reviewers should receive more education and training related to HBO therapy to better understand the treatment and give more complete answers to provider questions. In several interviews, HBO providers suggested that they often encounter MAC reviewers who do not have enough clinical experience with or knowledge about HBO therapy to respond adequately to providers' substantive questions.

Domain 6. Scalability/implications

Domain 6: Scalability/implications

MAC staff generally support expanding the model to additional states. They believe the model is effective in limiting the medically unnecessary use of HBO therapy. They did, however, express some concerns with the coverage policies underlying the HBO medical necessity requirements and guidelines, as the NCD may be outdated.

Multiple MAC and HBO staff interviewed recommended that the current NCD and/or LCD for HBO) may be obsolete. They suggested that they be modified to reflect the most current evidence-based practice recommendations, which may change over time based on accumulated research.

HBO providers suggest the model would benefit from additional efforts to incorporate their expertise in the refinement of the HBO prior authorization process. They are especially interested in providing input on the medical necessity guidelines although these are not an operational component of the prior authorization model.

CMS CPI senior staff interviewed for the project felt that model was successful, but identified several challenges and considerations in their decision to not extend the model.

Stakeholder suggestions for improving the prior authorization model

Generally, MAC staff we interviewed view the HBO prior authorization model as highly effective and efficient, and believe it should be implemented in other states; many recommended doing so to realize additional cost savings. There were concerns, however, with the coverage policies that underlie the HBO eligibility requirements. A significant issue MAC staff raised during interviews was a concern that the HBO NCD may be outdated. Multiple respondents noted this and recommended that CMS review the NCD in light of current evidence-based practice, as treatment protocols change over time based on accumulated research. MAC staff also noted that there are several conditions for which providers believe HBO would be appropriate and useful that are not included in the current version of the NCD, and felt that a review of these conditions for inclusion might be warranted. Given the reliance of the Novitas (New Jersey) LCD on the most recent NCD, these changes would also impact the current LCD. However, changes to these policies are beyond the scope of the prior authorization model as it only serves to enforce existing rules and requirements.

In addition to updating the coverage rules, both MAC staff and HBO providers interviewed recommend that before expanding the model, CMS should meet with key stakeholders, including both MACs and HBO providers, to review the medical necessity guidelines to ensure their

consistent interpretation. HBO providers further suggested that key stakeholders including national organizations that focus on HBO care should be included in this review process.

Some respondents (including both MAC and HBO facility staff) felt that MACs and HBO providers would benefit from additional education and outreach addressing medical necessity guidelines and the PAR documentation and submission process. In addition, several MAC staff interviewed felt that CMS should have MACs extend these education efforts to HBO providers in states where the HBO model has not been implemented, as the same medical necessity guidelines are used in the prepayment review performed in non-model states. MAC personnel further suggested that educating providers in all states on HBO medical necessity guidelines would encourage consistent understanding, interpretation, and application of guidelines. HBO providers offered a similar suggestion about extending education efforts, feeling that by providing prior authorization education to all providers who might refer patients for HBO, CMS could improve documentation quality and make the submission process more efficient.

Other recommendations from HBO providers include requiring a shorter time period for PAR decisions from the current 10 days, as well as allowing the submission of summarized medical notes and documentation in the place of original lengthy medical records. They feel these recommended changes would reduce the delay that they believe some eligible patients experience in being affirmed and receiving HBO therapy.

CMS CPI Perspectives

In October 2017, we conducted a semi-structured, in-person interview with three senior staff members from the CMS Center for Program Integrity (CPI). The interview focused on HBO prior authorization model implementation and operation, perceived impact and effectiveness of the model, as well as challenges to model expansion. Interviewees cited successes and challenges that were consistent with the HBO evaluation findings. They noted that the Undersea and Hyperbaric Medical Society (UHMS) played a supportive role in developing the HBO model and its guidelines in the preliminary stages of implementation. It was also helpful to CMS to learn about the role and perspective of important provider groups, including HBO management companies. Overall, interviewees believe that the model was successful in reducing costs and limiting treatment to appropriate cases. They believe that over time, resubmissions declined, reflecting improvements in provider comprehension of the model and in the documentation providers submitted to the MACs for review in the initial submission of the PAR.

Interviewees believe that there could have been spillover of the effects of the prior authorization model to non-model states and this could have been manifested through education on and enforcement of existing guidelines by the MACs. They believed that this spillover, if present, could have resulted in savings in non-model states in addition to savings in the model states.

According to interviewees, HBO model challenges included the effects of having NCD and LCD differences across states, which led to lower rates of approval in New Jersey where a LCD was used. Interviewees discussed the need for MACs to present to providers all of the reasons for non-affirmation of a prior authorization request at the onset of submission, in an effort to reduce resubmissions and confusion among providers. In addition, the interviewees believed that providers often requested more specific information and definitions from CMS and the MACs,

reflecting the need for providers and all stakeholders to receive more communication, outreach, and education. They noted that the lack of specific non-affirmation codes that clarify why a PAR was not affirmed also resulted in provider concern and confusion, and these specific codes would have been beneficial.

The interviewees noted that CMS received approval for a three-year model that is ending on schedule without request for extension. They noted that several factors are considered in deciding whether to expand a model, including total savings, outcomes and potential deterrence, and overall potential for success. In the case of HBO prior authorization, interviewees agreed that the model realized savings but noted that other strategies can be considered in the future to achieve similar or greater results, and that these strategies can account for burden and the needs of different populations. At the same time, the interviewees indicated that prior authorization would remain a viable option for use in the future.

This page has been left blank for double-sided copying

CONCLUSION

The prior authorization model decreased HBO service use and expenditures; however, the decrease in total Medicare expenditures is not statistically significant. The reductions observed in total Medicare expenditures vary considerably by state, but are not statistically significant in any state. At the same time, we have not found clear, quantitative impacts on quality of care, adverse outcomes, or access to care either across states or for the rural and dual eligible subgroups. Since CMS selected states to participate in the model based on their previous high use of HBO services, it is possible that a nationwide prior authorization program would achieve lower savings than evidenced here, as the possibility for savings in other states may not be as great as in the HBO model states.

Despite the lack of quantitative findings pointing to poor quality of care and increased adverse outcomes, some stakeholders believe that the HBO model results in beneficiaries experiencing delays in receiving needed treatment. These stakeholders are concerned that the model could have a negative impact on quality by curtailing HBO use.

As we noted previously, Novitas (the MAC for New Jersey) uses a local coverage determination to guide prior authorization determinations in that state which was more stringent than the national coverage determinations. The model appears to have a more substantial impact on HBO utilization and costs in New Jersey than it does in the other model states. These findings raise the possibility that national implementation of prior authorization using only national coverage determinations might not be as successful at reducing utilization and cost as our overall results suggest. At the same time, the model clearly was effective in each of the three states and we cannot be certain that the greater impact observed in New Jersey was due to Novitas' use of its local coverage determination. Without knowing why the model affected New Jersey differently from the other states, it is difficult to know how large an impact the model would have if scaled nationally.

Operationally, the HBO prior authorization model had a number of challenges. These included:

- Stakeholder education. Educating stakeholders, especially providers, about the requirements of the model is important to smooth operations and to stakeholders' perceptions of the model's success. While effort were undertaken to educate and inform providers by the MAC staff, the variation in interaction between MACs and providers makes it challenging to ensure a base level of understanding. Some providers were initially confused about the requirements for submitting prior authorization requests and specific medical necessity requirements for beneficiaries to be eligible for prior authorization, although documentation requirements were in place prior to the model's implementation. Over time, however, stakeholders reported that, through education efforts, understanding of the requirements increased and thus the quality of HBO providers' documentation improved.
- Stakeholder concern about Medicare's coverage rules and medical necessity criteria. The HBO prior authorization model enforces existing coverage rules and does not create or modify them. One of the concerns raised by providers is that the coverage and medical

necessity criteria used were dated and did not reflect advances in care delivery. There were also provider and beneficiary concern related to beneficiaries who had previously utilized services but will no longer receive them because the existing medical necessity criteria are now more rigorously enforced.

- Delay in treatment. Early in a prior authorization model, prior authorization requests may take longer than expected to be affirmed, especially for those beneficiaries that are initially not approved and require further documentation. In addition, existing coverage requirements – which may have not be consistently enforced prior to the model – mandated that beneficiaries first receive a standard course of treatment and that treatment be proved to be unsuccessful before HBO is rendered. Both of these scenarios could result in delay in starting HBO, which has the potential to affect the success of treatment. At the same time, our empirical analysis did not consistently identify quality of care problems and adverse impacts that are often associated with treatment failure.
- Provider administrative burden. Providers reported significant burden meeting the documentation requirements of the model, although these requirements were already in place but had not been consistently enforced previously.

Study limitations

In the descriptive analysis, we observed a steep decline in HBO use in both the treatment and certain comparison states around the time the model went into effect, raising the possibility of a spillover or deterrence effect (these are described on pages 8 and 9). Such effects would understate our estimates the model's impacts on utilization, cost, and quality. To address the possibility of a spillover or deterrence effect, we performed additional analyses. We found the declines in HBO use and costs did occur in some, but not all, comparison states as well as in some states served by MACs not involved in the model. Our analyses suggests that spillover and deterrent effects are either not present or are very small.

Our study has other limitations. First, given CMS's choice of model states with particularly high rates of historical HBO service utilization, the evaluation had to rely on a quasi-experimental design with comparison states rather than on the gold standard of random assignment, which limits the external validity of the findings and renders conclusions about causality less definitive. Second, most of the primary qualitative data collection for the evaluation relied on nonprobability samples of stakeholder groups (HBO providers and beneficiaries) that were recruited through an aggressive outreach effort. This sampling approach, while necessary, does not guarantee that we identified and included in the sample all potentially affected stakeholders in the model states. In addition, beneficiaries who participated in interviews were selected through samples of convenience and were identified and recruited with the help of HBO facility staff as part of the site visits. In these instances, stakeholders with strong opinions, a greater stake in model impacts or with particularly noteworthy experiences may be more likely than others to participate, and their views may not represent the experiences and perceptions of the full stakeholder population.

REFERENCES

American Medical Association. "2013 National Health Insurer Report Card." Chicago, IL: AMA, 2013.

Asher, Andrew, Purcell, Kristen, Contreary, et al. "First Interim Evaluation Report of the Medicare Prior Authorization Model for Repetitive Scheduled Non-Emergent Ambulance Transport (RSNAT)". Washington, DC: Mathematica Policy Research, February 2018.

Bergeson, Joette Gdovin, Karen Worley, Anthony Louder, Melea Ward, and John Graham. "Retrospective Database Analysis of the Impact of Prior Authorization for Type 2 Diabetes Medications on Health Care Costs in a Medicare Advantage Prescription Drug Plan Population." *Journal of Managed Care Pharmacy,* vol. 19, no. 5, 2013, pp. 374–384.

Centers for Medicare and Medicaid Services (CMS). "Medicare Prior Authorization of Power Mobility Devices Model Status Update." 2014. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/PMDDemoDecemberStatusupdate12302014.pdf. Accessed May 1, 2015.

CMS. National Coverage Determination (NCD) for Hyperbaric Oxygen Therapy (20.29). Available at https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=12&ver=3. Accessed December 5, 2017.

CMS. "Prior Authorization of Non-Emergent Hyperbaric Oxygen." Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Prior-Authorization-Initiatives/Prior-Authorization-of-Non-Emergent-Hyperbaric-Oxygen.html. Accessed December 5, 2017.

CMS. "National Coverage Determination (NCD) for Hyperbaric Oxygen Therapy (20.29)." Publication No. 100-03. Available at https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35021&ContrId=332&ver=116&ContrVer=1&CntrctrSelected=332*1&Cntrctr=332&name=Novitas+Solutions%2c+Inc.+(04211%2c+A+and+B+MAC%2c+J+-+H)&s=All&DocType=All&bc=AggAAAQAAAAA&. Accessed May 1, 2015.

Department of Health and Human Services (DHHS). "Hyperbaric Oxygen Therapy: Its Use and Appropriateness." OEI 06-99-00090. Washington, DC: Office of the Inspector General, 2000.

DHHS. "Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs." *Federal Register*, February 12, 2015, pp. 7912–7966.

MacKinnon, Neil, and Ritu Kumar. "Prior Authorization Programs: A Critical Review of the Literature." *Journal of Managed Care Pharmacy,* vol. 7, no. 4, 2001, pp. 297–302.

McHugh, M.L. "Interrater Reliability: The Kappa Statistic." *Biochemia Medica*, vol. 22, no. 3, 2012, pp. 276–282.

National Government Services. "Medical Review Focus Areas: Illinois Non-Emergent Hyperbaric Oxygen Prior Authorization Requests." Available at https://www.ngsmedicare.com/ngs/portal/ngsmedicare/newngs/home-lob/pages/complianceandaudits/medical-review/medical-review-focus-areas/b_illinois%20non-emergent%20hyperbaric%20oxygen%20prior%20authorization%20requests/!ut/p/a1/zVPLkoIwEPwV_AAqQcLDI6-1fCCK5SpcrIBBUwJhA1qrX79hn1501yoPm1tPdc30dKZBDFYgLvGRbnFDWYnzFsf6GlkDT1EcOOoPBxq05tPZ4hmFCjQVsAQxiGt8JClje0palOYE8x8Yev1BMAGRA-JNXfmjbVusUroBEUKZnvV6SM5MRZURMlTZRJDIGw1BJTE0rZeqLXsc2CCaYt5ItlAUCUXwyrPgnwRfUgI1MKGFnmzXnU3Vvt39JNwYEQkNxtUhgQHmd-54uyFCHw2Xjr-eLbxQsC8cF-jScQG_HAfRpXEPVaT_O0Xao02__xeHv92euN0u9x1fRKDCzU6mZcbAKlnTPKclo7VUslImBeFbUjbS7lQRnmBOU4m9nkRJqjhlXMKHZsc4Pb9nVOLk5UDqpgZL9ztgVbEPveScjfXQhKpWbS33nBWFZU0nMk7aUn4cWJ3OG2iqA9s!/dl5/d5/L2dBISEvZ0FBIS9nQSEh/?clearcookie=&savecookie=&REGION=&LOB=Part%20B. Accessed December 5, 2017.

Novitas Solutions. "HBO (Hyperbaric Oxygen) Therapy Prior Authorization Request – Medical Record Checklist." Available at https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00110161&_afrLoop=172232842456970#!%40%40%3F_afrLoop%3D172232842456970%26centerWidth%3D100%2525%26contentId%3D00110161%26leftWidth%3D0%2525%26rightWidth%3D0%2525%26showFooter%3Dfalse%26showHeader%3Dfalse%26_adf.ctrl-state%3Dc2hwu0dp8_33. Accessed December 5, 2017.

TRICARE. "Prior Authorization." Available at http://www.tricare.mil/CoveredServices/Pharmacy/Drugs/PriorAuth?sc_database=web. Accessed May 14, 2015.

This page has been left blank for double-sided copying.

www.mathematica-mpr.com

Improving public well-being by conducting high quality, objective research and data collection

PRINCETON, NJ ■ ANN ARBOR, MI ■ CAMBRIDGE, MA ■ CHICAGO, IL ■ OAKLAND, CA ■ TUCSON, AZ ■ WASHINGTON, DC ■ WOODLAWN, MD