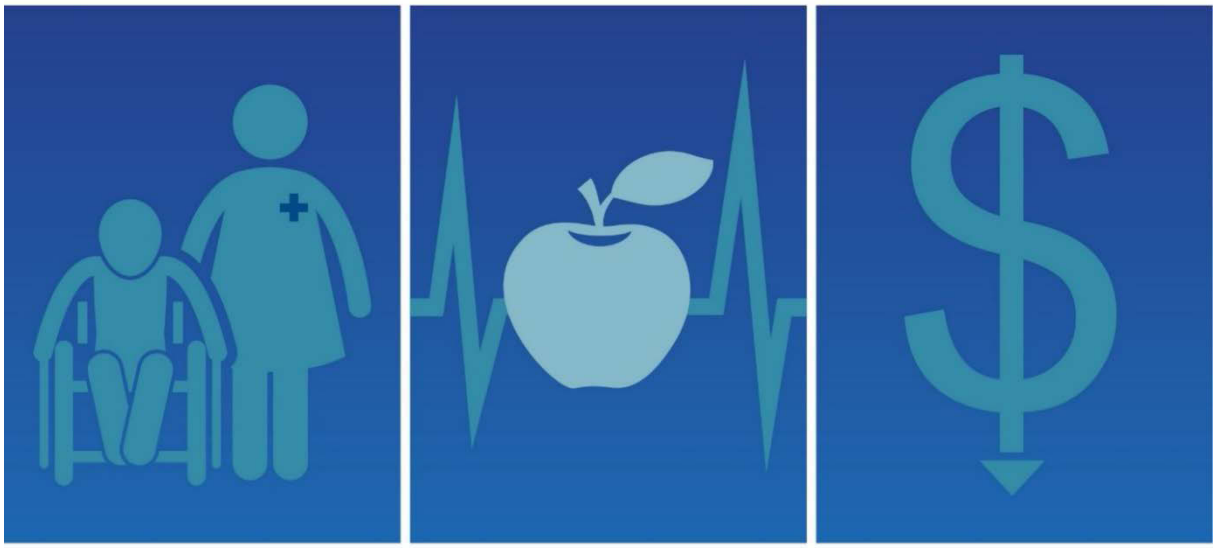
MATHEMATICA
Policy Research

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

HHSM-500-2014-00034
June 2018

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



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

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

CONTENTS

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

TABLES

FIGURES

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

APPENDIX A

HBO COMPARISON GROUP SELECTION

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

The purpose of this appendix is to describe our approach for selecting a set of matched-comparison states.

As the report notes, the evaluation uses a difference-in-difference design that estimates the effect of the prior authorization model as the difference between the change in outcomes in the model states versus the change in outcomes in another set of states. An important part of the design is the choice of the comparison states that permits the comparison with the model states; the outcomes for the comparison states are termed the counterfactual outcomes. Given that a well-chosen counterfactual reduces the need for the outcome analyses to depend as critically as it otherwise would on the multivariate analyses' modeling specifications, it is important to choose a set of comparison states that are as similar as possible to the model states. It is also important to select a comparison group that minimizes the risk of obtaining misleading results due to the confounding influence of unobserved factors.

To maximize the internal validity of the difference-in-difference analytic approach, we must choose a set of comparison states that are as similar as possible to the model states on both observed and unobserved characteristics in the period before implementation of prior authorization. A simple unadjusted comparison of the model states to all other non-model states could be misleading, particularly since CMS chose the states with the highest HBO service utilization and highest rates of improper claims as those for initial implementation of the prior authorization model.

The goal of the comparison group selection effort is to select a set of comparison states for the impact analysis that represent a valid counterfactual to the model states. One approach to selecting such a comparison group is to match a set of states to the model states based on a set of observed characteristics that theory or prior evidence suggest are related to the likelihood of both being subject to the prior authorization model and to the outcome measures. Various statistical matching or weighting approaches can be used to make this comparison group selection.

However, such a matching approach can only balance the model and comparison states on observed characteristics. Unobserved characteristics may remain unbalanced and may potentially confound the analysis, particularly those that are unassociated with the observed characteristics. Thus, it is often preferable to first select a comparison group that appears likely to be balanced on unobservable characteristics, then investigate the need to further balance on observable characteristics (Cook et. al, 2008). This approach increases the likelihood of balance on both observed and unobserved factors.

To implement this approach, we first limited our set of potential comparison states to the states within the same Medicare Administrative Contractors (MACs) jurisdictions as those servicing the model states. Because prior authorization is implemented by the MACs, a natural counterfactual to the prior authorization condition are the states administered by the same MACs but not subject to prior authorization. These comparison states are subject to many of the same policies and administrative processes as the model states except for prior authorization. Other MACs may have different policies and administrative processes which could confound the impact analysis. Table A.1 shows the model states and comparison states by MAC.

Table A.1. Model and Comparison States by MAC

MAC	Prior authorization model state	Non-prior authorization comparison states
National Government Services	Illinois	Minnesota, Wisconsin
Wisconsin Physicians Service Insurance Corporation	Michigan	Indiana
Novitas Solutions	New Jersey	Delaware, District of Columbia, Maryland, Pennsylvania, Virginia[a]

[a] Limited to Arlington & Fairfax counties and Alexandria city (District of Columbia market area).

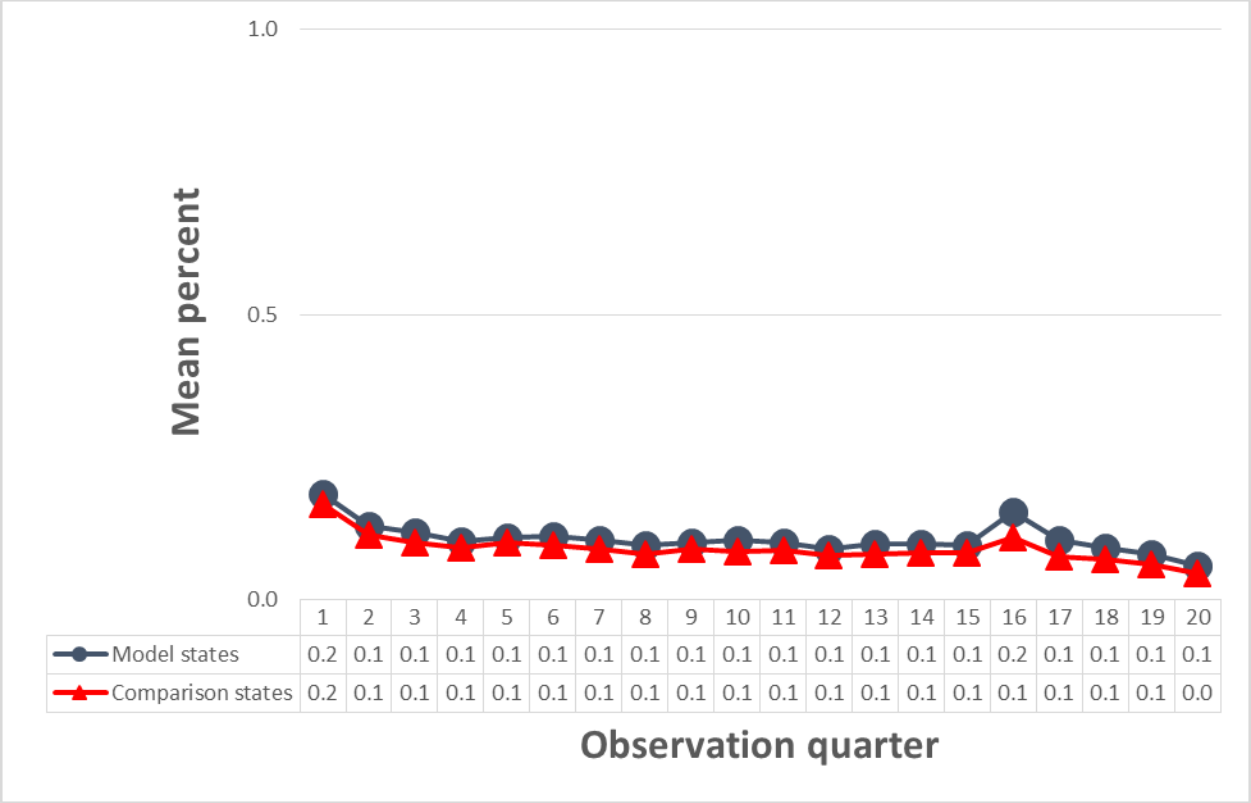
Source: https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/MACs-by-State-July-2016.pdf

We limited the comparison states to those within the same MACs as the model states to increase the likelihood of achieving balance on unobserved characteristics related to the administration of HBO Medicare claims. The second step in our selection process involved determining how well the model and comparison states were balanced on observed factors. Figures A.1-A.5 present several indicators related to the Medicare beneficiary populations, HBO service providers, and HBO utilization separately for the model and comparison states for each quarter observed in our analysis data. Perfect balance on these measures is not required since we weighted beneficiaries for the impact analysis based on a range of characteristics (refer to Appendix D for more details). What is important is that the model and comparison *states* are similar on each measure.[1]

As the figures show, the model and comparison states are well balanced on all but one of these measures. The beneficiaries in the comparison states are more likely to live in a rural area, but the difference in this measure can be reduced using weighting. As a result, we did not further restrict the set of comparison states for this analysis. We believe the model and comparison states are well-balanced on observable characteristics. We also believe they are balanced on key unobservable characteristics because of our choice to select comparison states from among the same MACs as the model states.

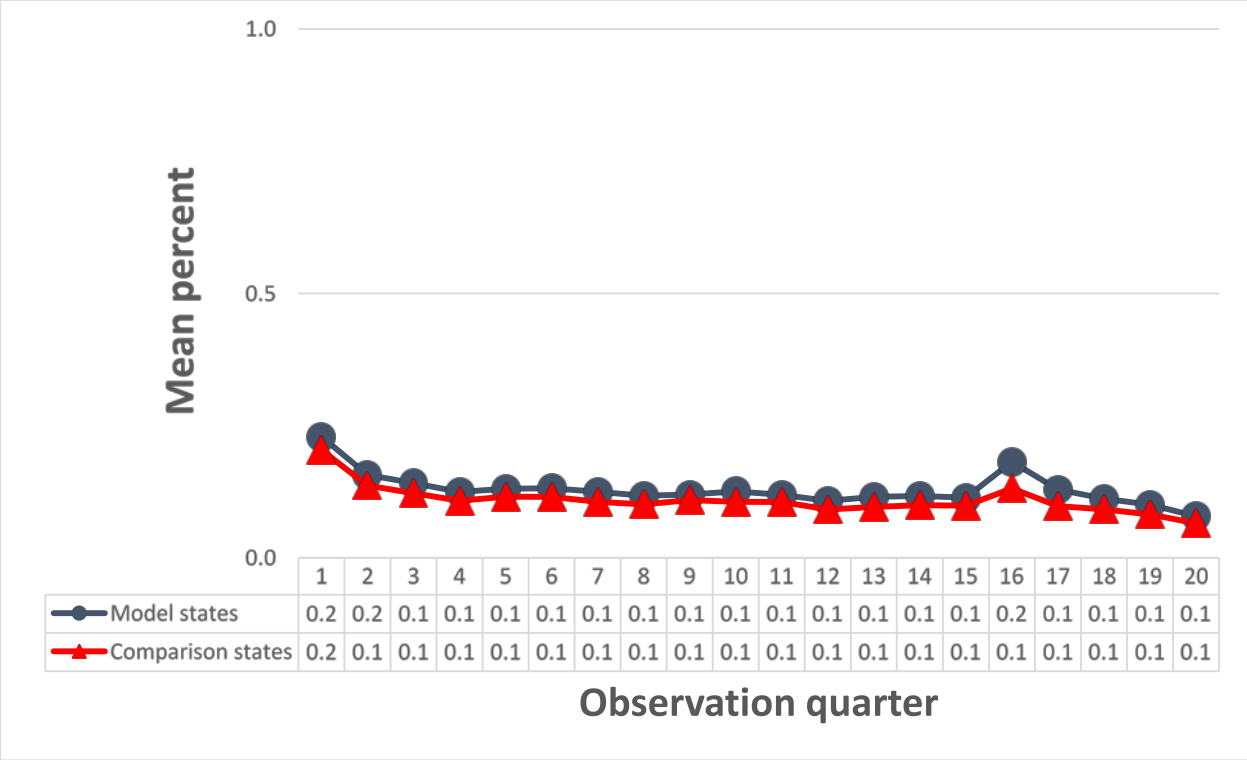
[1] When reviewing the figures, it is important to note that the vertical axis varies between figures as the rates of some characteristics are extremely rare.

Figure A.1. Mean percent beneficiaries with diabetic ulcers of the lower extremities



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Model states	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.1	0.1	0.1	0.1
Comparison states	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.0

Figure A.2. Mean percent beneficiaries with any condition associated with HBO treatment



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Model states	0.2	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.1	0.1	0.1	0.1
Comparison states	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1

Figure A.3. Mean percent rural beneficiaries

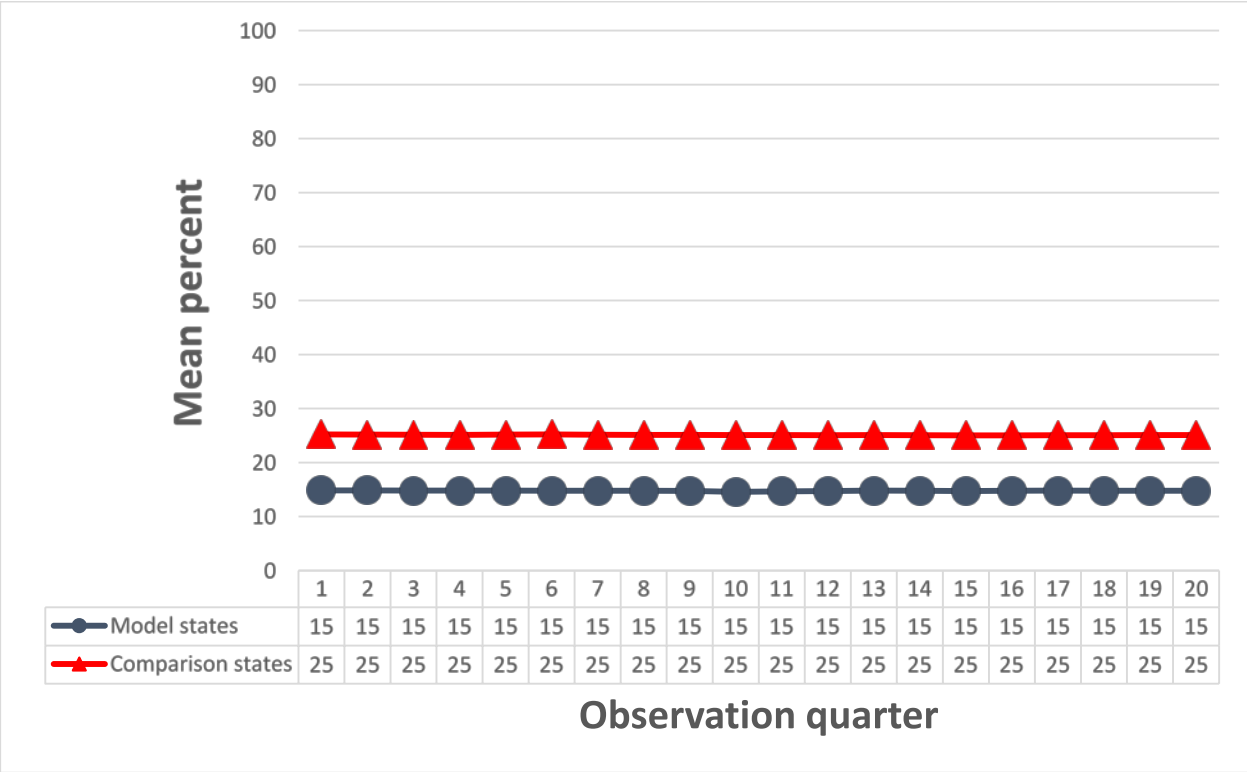
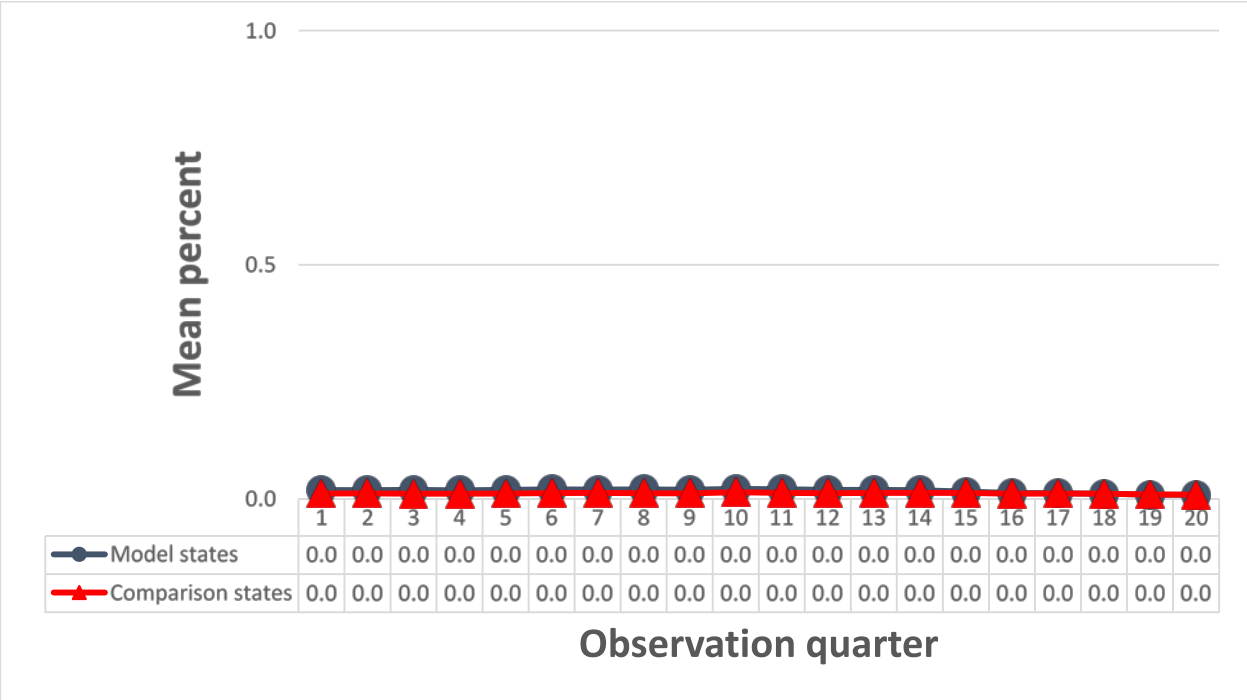
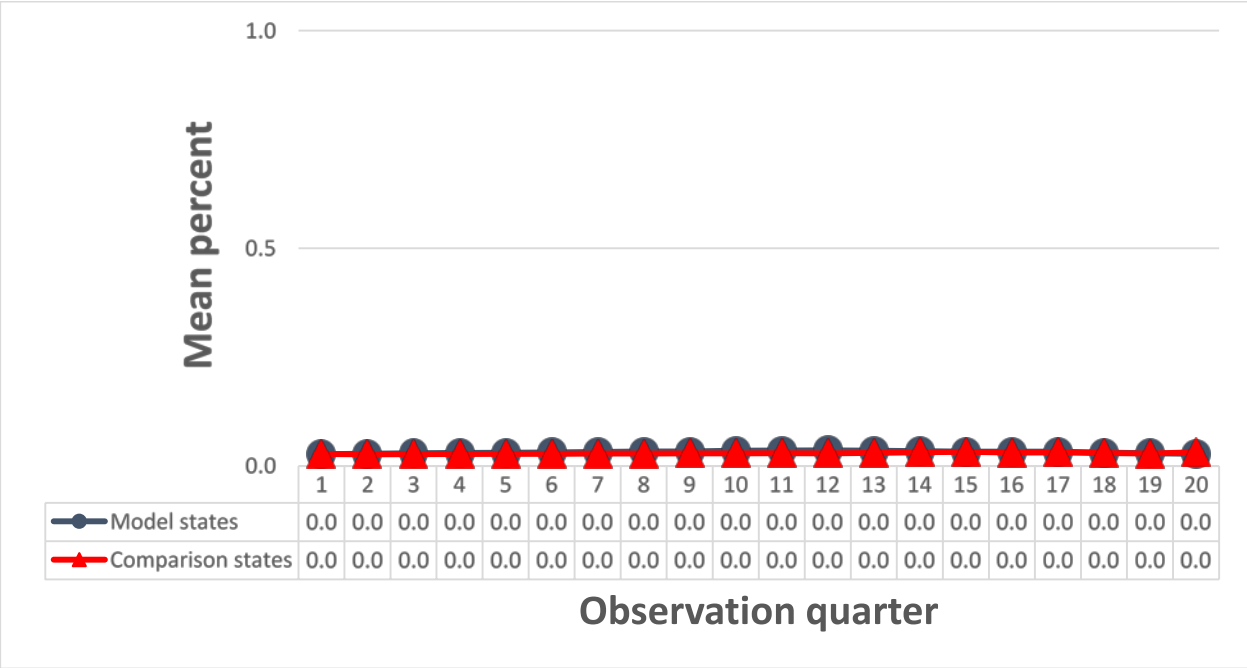


Figure A.4. Mean percent of beneficiaries with at least one HBO procedure



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Model states	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Comparison states	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Figure A.5. Mean number of unique providers per 1,000 beneficiaries



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Model states	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Comparison states	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

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

APPENDIX B

QUANTITATIVE ANALYSIS

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

In this appendix we discuss the possibility of spillover effects from model states to comparison states, and describe analyses we conducted to assess the potential threat to our evaluation design. We then provide summary statistics, including demographic characteristics and baseline levels for each outcome measure. Finally, we include subgroup analyses for key subgroups of interest.

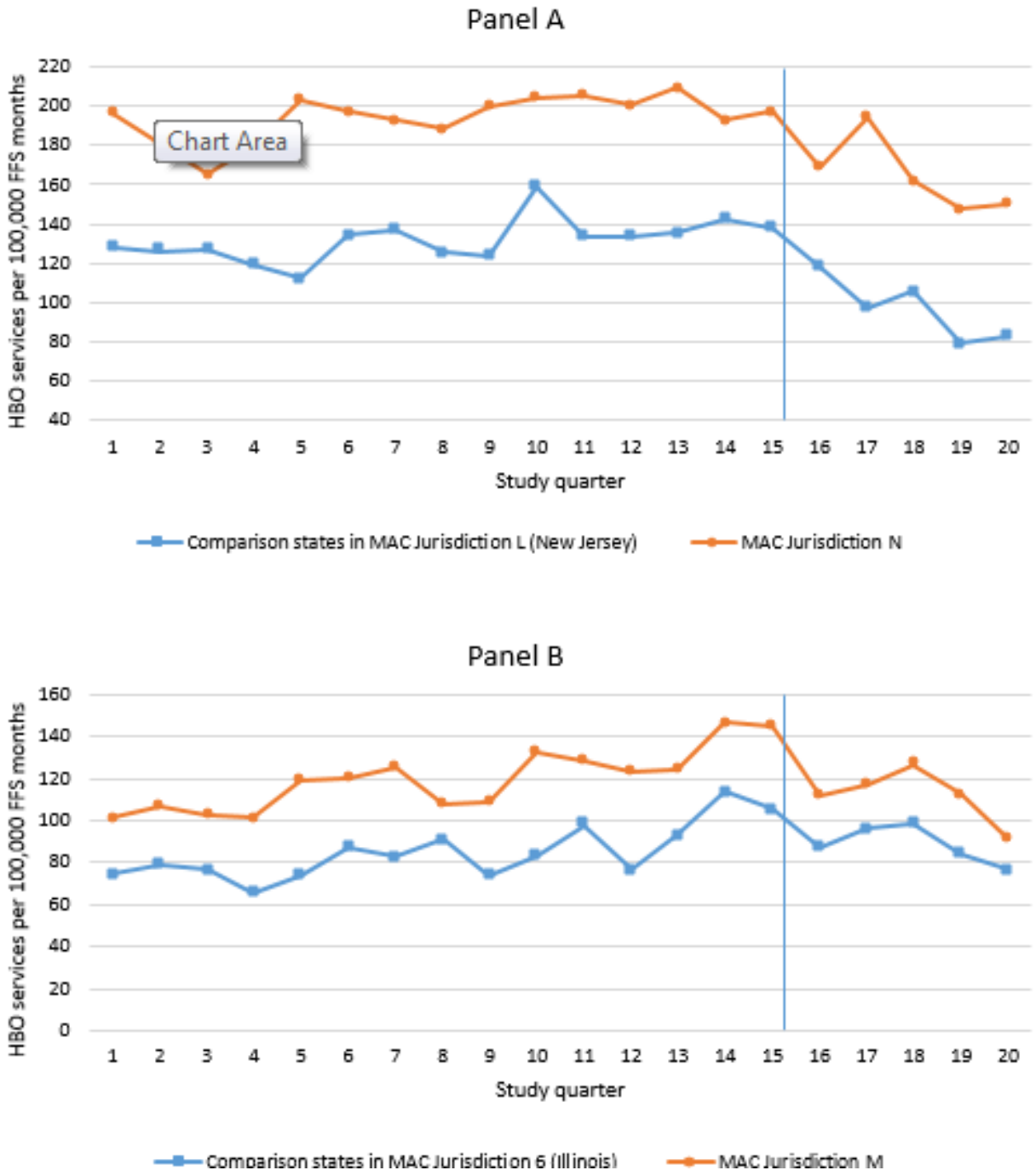
Is there evidence of a spillover effect?

Our comparison group strategy uses states that are in the same MAC jurisdiction as the model states, but which were not subject to prior authorization. If claims processing for the comparison group changed as a result of the model (if, for example, claims edits or human reviewers were stricter in evaluating claims from comparison states following model implementation than previously), our regression analyses will underestimate the true impact of the model. To assess the likelihood of such spillovers, we created state-level measures of HBO utilization normalized to the Medicare population (number of HBO services reimbursed per 100,000 FFS months). We looked at the trends in utilization in each of the 12 Medicare Part A/B MAC jurisdictions, removing the model states from their respective MACs to look only at trends in utilization in the comparison states. 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 around the time of model implementation.

Figure B.1 shows how utilization changed over time in the comparison states in two of our included MACs and in two MACs unaffected by the prior authorization requirement. Panel A includes the comparison states in MAC Jurisdiction L (Novitas, for New Jersey), which exhibited the sharpest drop-off in utilization at the time of the model start date. Panel B shows utilization in the comparison states in MAC Jurisdiction 6 (Illinois), which experienced a smaller decline following model implementation. Both are shown alongside utilization trends in MACs unaffected by the prior authorization model.

We cannot rule out that within-MAC spillovers affected the states in our comparison group (particularly in New Jersey's comparison states of Delaware, the District of Columbia, Maryland, Pennsylvania, and Arlington and Fairfax counties and the city of Alexandra in Virginia), but we similarly cannot rule out that changes observed in the comparison states are part of a larger national trend driving utilization downward around the same time as prior authorization went into effect in the model states. This broader trend could be associated with a number of factors, including changing practice patterns or the ICD-9 to ICD-10 changeover in coding systems. Another possibility is that HBO facilities—which include a number of national, multi-site organizations—may have anticipated stricter enforcement of existing HBO requirements, which are in effect in non-model states even if they are not rigorously enforced at present. These organizations may have pre-emptively taken a more cautious approach to HBO treatment and, in a number of locations, implemented some or all of the criteria used by the MACs in the model states. If present, spillover or sentinel effects will result in our estimates being biased towards zero since the comparison states would also be influenced by the model.

Figure B.1. HBO utilization in comparison states and unaffected MACs, by quarter



Notes: MAC Jurisdiction L contains Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, the counties of Arlington and Fairfax in Virginia, and the city of Alexandria in Virginia. Jurisdiction N contains Florida, Puerto Rico, and U.S. Virgin Islands. Jurisdiction 6 contains Illinois, Minnesota, and Wisconsin. Jurisdiction M contains North Carolina, South Carolina Virginia (except the localities included in Jurisdiction L), and West Virginia. Quarter 1 begins on January 1, 2012. Vertical line indicates start of prior authorization model in August 2015.

Beneficiary summary statistics

After applying the calibration weights, beneficiaries in comparison states are similar to those in treatment states on nearly all of the baseline demographic and health characteristics we examined, with group differences of less than 10 percent of the treatment group mean. The exception is a higher proportion of comparison state beneficiaries who are dually eligible for Medicare and Medicaid. Table B.1A contains weighted summary statistics for FFS beneficiaries with diabetic lower extremity wounds in treatment and comparison states. Table B.1B contains weighted summary statistics for FFS beneficiaries with any included condition in treatment and comparison states.

Table B.1A. Beneficiary summary statistics at baseline (weighted) among beneficiaries with diabetic lower extremity wounds

	Treatment mean (SD)	Comparison mean (SD)	Difference	Percentage difference (%)
Age (years)	71.39 (12.23)	71.04 (12.52)	0.35***	0.49
Female (%)	43.36 (49.56)	42.95 (49.50)	0.41	0.95
Race (%)				
White	76.68 (42.29)	76.34 (42.50)	0.34	0.44
Black	18.94 (39.19)	19.32 (39.48)	-0.38	-2.00
Other	4.38 (20.46)	4.34 (20.37)	0.04	0.97
Rural (%)	13.47 (34.14)	13.73 (34.41)	-0.26	-1.93
Dual (%)	26.47 (44.12)	26.86 (44.32)	-0.39	-1.47
HCC score	2.78 (1.97)	2.60 (1.85)	0.18***	6.45
Number of beneficiaries	**69,760**	**66,885**		

Note: Table presents weighted means (and standard deviations) of beneficiary characteristics for beneficiaries with diabetic lower extremity wounds from dates of service from April 2012 through December 2016. Comparison group individuals are weighted to resemble treatment group individuals on baseline demographic and health characteristics.

*p < 0.05, **p < 0.01, ***p < 0.001.

Table B.1B. Beneficiary summary statistics at baseline (weighted) among beneficiaries with any included condition

	Treatment mean (SD)	Comparison mean (SD)	Difference	Percentage difference (%)
Age (years)	71.33 (12.54)	70.97 (12.92)	0.36***	0.51
Female (%)	43.42 (49.56)	43.05 (49.52)	0.36	0.84
Race (%)				
White	77.48 (41.77)	76.95 (42.11)	0.52	0.67
Black	18.24 (38.61)	18.94 (39.18)	-0.71*	-3.87
Other	4.29 (20.26)	4.11 (19.84)	0.18	4.29
Rural (%)	13.48 (34.15)	13.68 (34.36)	-0.21	-1.53
Dual (%)	25.93 (43.82)	26.55 (44.16)	-0.62*	-2.39
HCC score	2.74 (2.02)	2.59 (1.93)	0.15**	5.38
Included Condition (%)				
Diabetic lower extremity wounds	81.29 (39.00)	80.00 (40.00)	1.29***	1.59
Osteomyelitis	14.29 (35.00)	15.56 (36.25)	-1.27***	-8.88
Irradiation cystitis	3.01 (17.09)	3.21 (17.64)	-0.20*	-6.75
Soft tissue radionecrosis	4.08 (19.78)	4.31 (20.30)	-0.23*	-5.60
Osteoradionecrosis	2.45 (15.45)	2.58 (15.84)	-0.13	-5.28
Actinomycosis	1.61 (12.60)	1.61 (12.60)	-0.001	-0.05
Number of beneficiaries	**85,816**	**81,495**		

Note: Table presents weighted means (and standard deviations) of beneficiary characteristics for beneficiaries with any included condition from dates of service from April 2012 through December 2016. Comparison group individuals are weighted to resemble treatment group individuals on baseline demographic and health characteristics.

*p < 0.05, **p < 0.01, ***p < 0.001.

Utilization and expenditures

Tables B.2A and B.2B show the baseline levels of the beneficiary utilization and expenditure outcome measures per beneficiary per quarter for the beneficiary population we examined. Before the model was implemented, beneficiaries in treatment states had higher quarterly utilization of and expenditures on HBO services.

Table B.2A. Baseline quarterly utilization and costs per beneficiary among beneficiaries with diabetic lower extremity wounds (weighted)

	Treatment mean (SD)	Comparison mean (SD)	Difference	Percent difference (%)
Probability of HBO utilization (%)	1.87 (13.54)	1.47 (12.05)	0.39***	21.12
Number of HBO treatments	0.37 (3.39)	0.27 (2.73)	0.11***	28.20
Probability of HBO utilization with appropriate history of standard therapy (%)	0.22 (4.69)	0.16 (3.98)	0.06**	28.01
Number of HBO treatments with appropriate history of standard therapy	0.04 (1.19)	0.03 (0.86)	0.02***	38.49
HBO expenditures ($)	162.77 (1,496.71)	115.00 (1,219.82)	47.77***	29.35
HBO and standard therapy expenditures ($)	165.34 (1,516.57)	117.13 (1,244.50)	48.21***	29.16
Total Medicare FFS expenditures ($)	15,687.10 (26,892.84)	13,680.20 (24,945.80)	2,006.91***	12.79
Number of observations	**258,437**	**259,388**		

Note: Table presents baseline weighted means (and standard deviations) of quarterly beneficiary utilization and payment outcomes for beneficiaries with diabetic lower extremity wounds from dates of service from April 2012 through December 2016. Comparison group individuals are weighted to resemble treatment group individuals on baseline demographic and health characteristics.

*p < 0.05, **p < 0.01, ***p < 0.001.

Table B.2B. Baseline quarterly utilization and costs per beneficiary among beneficiaries with any included condition (weighted)

	Treatment mean (SD)	Comparison mean (SD)	Difference	Percent difference (%)
Probability of HBO utilization (%)	1.89 (13.63)	1.53 (12.29)	0.36***	18.92
Number of HBO treatments	0.38 (3.42)	0.28 (2.81)	0.10***	25.90
HBO expenditures ($)	166.76 (1,513.92)	121.51 (1,257.21)	45.25***	27.14
Total Medicare FFS expenditures ($)	15,054.60 (26,542.79)	13,450.85 (25,365.44)	1,603.75***	10.65
Number of observations	**320,451**	**314,842**		

Note: Table presents baseline weighted means (and standard deviations) of quarterly beneficiary utilization and payment outcomes for beneficiaries with diabetic lower extremity wounds from dates of service from April 2012 through December 2016. Comparison group individuals are weighted to resemble treatment group individuals on baseline demographic and health characteristics.

*p < 0.05, **p < 0.01, ***p < 0.001.

Table B.3A. Impact of prior authorization on quarterly HBO utilization and cost among beneficiaries with any included condition, by rural residence and dual eligibility

	Probability of HBO utilization (percentage points) (I)	Number of HBO treatments (II)	Probability of HBO utilization with appropriate history of standard therapy (percentage points) (III)	Number of HBO treatments with appropriate history of standard therapy (IV)	HBO expenditures ($) (V)	Total Medicare FFS expenditures ($) (VII)
Rural status						
Rural						
Average marginal effect	-0.24†	-0.08*	-0.24†	-0.09*	-27.57†	-118.52
(standard error)	(0.13)	(0.04)	(0.13)	(0.04)	(19.55)	(352.34)
Baseline	1.86	0.38	1.84	0.36	155.38	11439.58
Change from baseline (%)	-13.15	-22.25	-13.26	-24.38	-17.74	-1.04
R^2	0.07	0.01	0.07	0.01	0.01	0.05
Not rural						
Average marginal effect	-0.36***	-0.08***	-0.39***	-0.09***	-65.35***	-251.5
(standard error)	(0.05)	(0.02)	(0.06)	(0.02)	(11.77)	(220.38)
Baseline	1.9	0.38	1.89	0.36	168.59	15634.98
Change from baseline (%)	-18.93	-22.05	-20.41	-25.87	-38.77	-1.61
R^2	0.08	0.01	0.08	0.01	0.01	0.07
Dual eligibility						
Dual eligible						
Average marginal effect	-0.22**	-0.06**	-0.26**	-0.07**	-50.14**	186.45
(standard error)	(0.08)	(0.02)	(0.08)	(0.02)	(16.05)	(382.95)
Baseline	1.53	0.28	1.53	0.27	122.83	17369.07
Change from baseline (%)	-14.61	-22.47	-17.3	-27.86	-40.82	1.07
R^2	0.08	0.01	0.07	0.01	0.01	0.07
Not dual eligible						
Average marginal effect	-0.39***	-0.10***	-0.40***	-0.10***	-63.38***	-404.92†
(standard error)	(0.06)	(0.02)	(0.06)	(0.02)	(12.88)	(222.43)
Baseline	2.03	0.42	2.02	0.39	183.32	14182.24
Change from baseline (%)	-19.00	-23.57	-19.89	-26.49	-34.57	-2.86
R^2	0.08	0.01	0.08	0.01	0.01	0.06

Note: The table presents average marginal effects and (standard errors) from weighted logistic (I and III), negative binomial (II and IV), and OLS (V, VI, VII) regression analyses using 187,208 rural and 1,033,254 non-rural beneficiary-quarters and 343,745 dual and 876,717 non-dual beneficiary-quarters for beneficiaries with diabetic lower extremity wounds from dates of service from April 2012 through December 2016. Control variables include age, age squared, sex, race, 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 included Illinois, Michigan, and New Jersey. The comparison states included Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

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

Table B.3B. Impact of prior authorization on quarterly HBO utilization and cost among beneficiaries with diabetic lower extremity wounds, by rural residence and dual eligibility

	Probability of HBO utilization (percentage points) (I)	Number of HBO treatments (II)	Probability of HBO utilization with appropriate history of standard therapy (percentage points) (III)	Number of HBO treatments with appropriate history of standard therapy (IV)	HBO expenditures ($) (V)	Total Medicare FFS expenditures ($) (VII)
Rural status						
Rural						
Average marginal effect	-0.23†	-0.04	-0.03	-0.04†	-31.40†	-236.24
(standard error)	(0.13)	(0.03)	(0.05)	(0.02)	(19.77)	(388.37)
Baseline	1.78	0.36	0.18	0.03	148.57	11697.66
Change from baseline (%)	-12.81	-10.72	-17.29	-115.56	-21.14	-2.02
R^2	0.04	0.01	0.03	0.02	0.003	0.05
Not rural						
Average marginal effect	-0.32***	-0.06***	-0.02†	-0.02*	-63.72***	-152.14
(standard error)	(0.06)	(0.01)	(0.02)	(0.01)	(12.69)	(246.76)
Baseline	1.88	0.37	0.23	0.05	165.06	16330.31
Change from baseline (%)	-16.86	-17.15	-10.36	-32.75	-38.60	-0.93
R^2	0.05	0.01	0.04	0.01	0.004	0.06
Dual eligibility						
Dual eligible						
Average marginal effect	-0.17*	-0.04†	0.02	0.00	-50.55**	195.26
(standard error)	(0.08)	(0.02)	(0.02)	(0.01)	(16.66)	(421.83)
Baseline	1.54	0.28	0.14	0.03	122.6	17924.54
Change from baseline (%)	-11.04	-13.52	12.49	10.99	-41.23	1.09
R^2	0.04	0.01	0.05	0.01	0.003	0.07
Not dual eligible						
Average marginal effect	-0.35***	-0.07***	-0.05*	-0.02*	-61.62***	-336.35†
(standard error)	(0.06)	(0.02)	(0.02)	(0.01)	(14.04)	(250.6)
Baseline	2.00	0.41	0.25	0.05	178.48	14811.93
Change from baseline (%)	-17.57	-17.7	-19.24	-39.46	-34.52	-2.27
R^2	0.05	0.01	0.04	0.01	0.004	0.06

Note: The table presents average marginal effects and (standard errors) from weighted logistic (I and III), negative binomial (II and IV), and OLS (V, VI, VII) regression analyses using 155,358 rural and 843,672 non-rural beneficiary-quarters and 288,891 dual and 710,139 non-dual beneficiary-quarters for beneficiaries with diabetic lower extremity wounds from dates of service from April 2012 through December 2016. Control variables include age, age squared, sex, race, 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 included Illinois, Michigan, and New Jersey. The comparison states included Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

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

Table B.4A. Baseline measures of quality of care and adverse outcomes among beneficiaries with diabetic lower extremity wounds (weighted)

	Treatment mean (SD)	Comparison mean (SD)	Difference	Percentage difference (%)
Proportion of HBO treatments with physician supervision	0.92 (0.22)	0.91 (0.24)	0.01	0.97
Probability of emergency department visit (%)	38.71 (48.71)	36.29 (48.08)	2.42***	6.25
Number of emergency department visits	0.68 (1.28)	0.63 (1.27)	0.05***	7.55
Probability of unplanned hospitalization (%)	31.10 (46.29)	28.11 (44.95)	2.99***	9.63
Number of unplanned hospitalizations	0.45 (0.89)	0.40 (0.82)	0.05***	11.95
Probability of death (%)	5.32 (22.44)	4.89 (21.56)	0.43***	8.09
Number of observations	**258,437**	**259,388**		

Note: Table presents baseline weighted means (and standard deviations) of quarterly beneficiary quality of care and adverse outcomes for beneficiaries with diabetic lower extremity wounds from dates of service from April 2012 through December 2016. Comparison group individuals are weighted to resemble treatment group individuals on baseline demographic and health characteristics.

*p < 0.05, **p < 0.01, ***p < 0.001.

Table B.4B. Baseline measures of quality of care and adverse outcomes among beneficiaries with any included condition (weighted)

	Treatment mean (SD)	Comparison mean (SD)	Difference	Percentage difference (%)
Proportion of HBO treatments with physician supervision	0.91 (0.22)	0.91 (0.24)	0.01	0.58
Probability of emergency department visit (%)	37.47 (48.41)	35.49 (47.85)	1.98***	5.29
Number of emergency department visits	0.66 (1.26)	0.62 (1.26)	0.04***	6.26
Probability of unplanned hospitalization (%)	30.10 (45.87)	27.63 (44.72)	2.47***	8.21
Number of unplanned hospitalizations	0.44 (0.87)	0.39 (0.82)	0.05***	10.35
Probability of death (%)	5.13 (22.07)	4.86 (21.50)	0.28***	5.40
Number of observations	**320,451**	**314,842**		

Note: Table presents baseline weighted means (and standard deviations) of quarterly beneficiary quality of care and adverse outcomes for beneficiaries with any included condition from dates of service from April 2012 through December 2016. Comparison group individuals are weighted to resemble treatment group individuals on baseline demographic and health characteristics.

*p < 0.05, **p < 0.01, ***p < 0.001.

Table B.5. Baseline measures of adverse outcomes related to diabetic lower extremity wounds (weighted)

	Treatment mean (SD)	Comparison mean (SD)	Difference	Percentage difference (%)
Probability of emergency department visit for lower extremity wound (%)	0.51 (7.12)	0.51 (7.15)	-0.004	-0.70
Number of emergency department visits for lower extremity wound	0.01 (0.08)	0.01 (0.08)	0.0001	1.47
Probability of unplanned hospitalization for lower extremity wound (%)	0.32 (5.66)	0.27 (5.18)	0.05**	16.23
Number of unplanned hospitalizations for lower extremity wound	0.003 (0.06)	0.003 (0.06)	0.0005**	15.99
Probability of amputation (%)	2.55 (15.76)	2.94 (16.89)	-0.39***	-15.27
Number of observations	**258,437**	**259,388**		

Note: Table presents baseline weighted means (and standard deviations) of quarterly beneficiary adverse outcomes related to diabetic lower extremity wounds from dates of service from April 2012 through December 2016. Comparison group individuals are weighted to resemble treatment group individuals on baseline demographic and health characteristics.

*p < 0.05, **p < 0.01, ***p < 0.001.

Table B.6A. Impact of prior authorization on quality of care and adverse outcomes among beneficiaries with any included condition, by rural residence and dual eligibility

	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)
Rural status						
Rural						
Average marginal effect	-0.01	-0.65	-0.02†	-0.51	0.00	-0.11
(standard error)	(0.02)	(0.53)	(0.01)	(0.46)	(0.01)	(0.19)
Baseline	0.94	36.39	0.66	27.10	0.38	4.65
Change from baseline (%)	-0.54	-1.78	-2.81	-1.90	-0.34	-2.43
R^2	0.05	0.03	0.02	0.03	0.02	0.06
Not rural						
Average marginal effect	-0.04†	-0.76**	-0.01†	-0.55*	0.00	-0.12†
(standard error)	(0.03)	(0.26)	(0.01)	(0.23)	(0.00)	(0.09)
Baseline	0.91	37.65	0.66	30.58	0.44	5.21
Change from baseline (%)	-4.60	-2.01	-1.38	-1.80	-0.89	-2.36
R^2	0.03	0.04	0.03	0.04	0.03	0.07
Dual eligibility						
Dual eligible						
Average marginal effect	-0.02	-0.76†	0.02	-0.34	0.00	-0.33†
(standard error)	(0.05)	(0.48)	(0.02)	(0.44)	(0.01)	(0.18)
Baseline	0.91	44.63	0.88	34.43	0.52	4.89
Change from baseline (%)	-1.73	-1.69	2.27	-0.99	0.47	-6.79
R^2	0.03	0.03	0.03	0.04	0.03	0.07
Not dual eligible						
Average marginal effect	-0.04	-0.74**	-0.02**	-0.63**	-0.01†	-0.04
(standard error)	(0.03)	(0.26)	(0.01)	(0.24)	(0.00)	(0.10)
Baseline	0.91	34.77	0.57	28.46	0.40	5.23
Change from baseline (%)	-3.97	-2.14	-3.32	-2.21	-1.43	-0.8
R^2	0.03	0.03	0.02	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 187,208 rural and 1,033,254 non-rural beneficiary-quarters and 343,745 dual and 876,717 non-dual beneficiary-quarters for beneficiaries with diabetic lower extremity wounds from dates of service from April 2012 through December 2016. Control variables include age, age squared, sex, race, 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 included Illinois, Michigan, and New Jersey. The comparison states included Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

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

Table B.6B. Impact of prior authorization on quality of care and adverse outcomes among beneficiaries with diabetic lower extremity wounds, by rural residence and dual eligibility

	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)
Rural status						
Rural						
Average marginal effect	-0.03	-0.77†	-0.02†	-0.76†	-0.01	-0.46*
(standard error)	(0.03)	(0.58)	(0.02)	(0.52)	(0.01)	(0.21)
Baseline	0.95	37.41	0.68	27.79	0.39	4.82
Change from baseline (%)	-2.98	-2.07	-3.09	-2.72	-1.70	-9.63
R^2	0.06	0.03	0.03	0.03	0.02	0.06
Not rural						
Average marginal effect	-0.05†	-0.78**	-0.01†	-0.53*	-0.00	-0.20†
(standard error)	(0.03)	(0.29)	(0.01)	(0.27)	(0.00)	(0.11)
Baseline	0.91	38.92	0.68	31.63	0.46	5.40
Change from baseline (%)	-5.67	-2.00	-1.47	-1.69	-0.59	-3.69
R^2	0.04	0.04	0.03	0.04	0.03	0.06
Dual eligibility						
Dual eligible						
Average marginal effect	0.00	-0.53	0.02†	-0.06	0.01	-0.41*
(standard error)	(0.05)	(0.52)	(0.02)	(0.48)	(0.01)	(0.20)
Baseline	0.91	45.55	0.90	35.21	0.54	5.04
Change from baseline (%)	-0.26	-1.17	2.63	-0.17	1.92	-8.05
R^2	0.03	0.03	0.03	0.04	0.03	0.07
Not dual eligible						
Average marginal effect	-0.03	-0.88**	-0.02***	-0.77**	-0.01†	-0.16†
(standard error)	(0.92)	(0.30)	(0.01)	(0.27)	(0.00)	(0.11)
Baseline	-6.07	36.04	0.60	29.5	0.42	5.43
Change from baseline (%)	0.04	-2.45	-3.71	-2.61	-1.97	-3.01
R^2	-0.03	0.03	0.02	0.03	0.02	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 155,358 rural and 843,672 non-rural beneficiary-quarters and 288,891 dual and 710,139 non-dual beneficiary-quarters for beneficiaries with diabetic lower extremity wounds from dates of service from April 2012 through December 2016. Control variables include age, age squared, sex, race, 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 included Illinois, Michigan, and New Jersey. The comparison states included Delaware, the District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, and Wisconsin.

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

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

APPENDIX C

QUANTITATIVE METHODS

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

This appendix contains detailed information on the analytic methods used in this evaluation. A brief overview is provided in the main body of the report, but readers interested in understanding our methodology in depth are advised to consult this appendix for the relevant information. We discuss analytic sample selection, selection and construction of outcome measures, methods for constructing descriptive figures, and detailed information about our regression approach.

Selection of conditions

Using the population of individuals in the three treatment states (New Jersey, Michigan, and Illinois) and seven comparison states (Indiana, Minnesota, Wisconsin, Pennsylvania, Maryland, Delaware, and the District of Columbia), and the time period 2012-2016, we selected beneficiaries who were diagnosed with one of the conditions for which prior authorization is required to receive HBO under the model:

1. Diabetic wounds of the lower extremities
2. Osteomyelitis
3. Soft tissue radionecrosis
4. Osteoradionecrosis
5. Actinomycosis

We identified these conditions using ICD-9 and ICD-10 diagnosis codes specified in the local coverage determination (LCD) used by Novitas (the MAC that processes claims from New Jersey and several other states) as supporting medical necessity for hyperbaric oxygen therapy (CMS, n.d.). We then supplemented with other measures selected internally. To be considered as having a condition, we required a beneficiary to have one inpatient claim featuring an included diagnosis code, or two outpatient claims on different dates within 90 days of each other, each featuring an included diagnosis code. We included individuals in our sample from the date of the first qualifying diagnosis.

Outcomes

We considered several quarterly outcomes related to utilization and cost (Domain 1), quality of care and adverse outcomes (Domain 2), and denied claims (Domain 5) (Table C.1). Some measures were created only for beneficiaries with a diabetic lower extremity wound, such as utilization with a history of standard wound therapy. We generated utilization outcomes by identifying claim lines that met the specified criteria and then aggregating each beneficiary's claim lines up to the quarter level. Outcomes related to HBO utilization and cost fall into the following two categories:

1. HBO service utilization: Claims for hyperbaric oxygen therapy (identified using HCPCS code 1300 before January 1, 2015 and HCPCS code G0277 after January 1, 2015) with or without physician supervision (identified using HCPCS code 99183).
2. HBO service utilization with other treatment: Claims for hyperbaric oxygen therapy with an appropriate history of standard wound therapy, as required in Medicare's National Coverage Determination (see Table C.2).

We also calculated total Medicare fee-for-service health care expenditures as the sum of claim line payment amounts across all claim types, including carrier, outpatient, inpatient, skilled nursing facility, home health, hospice, and durable medical equipment.

To assess whether there was evidence that the model resulted in unintended consequences, we examined impacts on quality and adverse outcomes for beneficiaries with diabetes and a lower extremity wound and for all beneficiaries for a condition requiring prior authorization. These outcomes measures are presented in Table C.1. Quality and adverse outcome measures included receipt of HBO with physician supervision, emergency department visits and inpatient admissions (both all-cause admissions and, for beneficiaries with diabetic lower extremity wounds, admissions specific to a lower extremity wound), amputations among beneficiaries with diabetic lower extremity wounds, and death. For all utilization measures, we considered both the likelihood of receiving any services in the quarter and the number of services received. The likelihood of receiving any services was represented as a binary variable equal to one if the beneficiary received at least one service in the category during the quarter. This approach allowed us to explore the degree to which the model impacts the number of individuals who receive services, the average number of services received by individuals, or both.

Table C.1. Outcome measures used in quantitative analyses

Measure	Beneficiaries with diabetes and lower extremity wound	All beneficiaries with a condition requiring prior authorization
Domain 1: Utilization and expenditures		
Utilization		
Receipt of HBO (binary and the number of HBO services)	✓	✓
Receipt of HBO with appropriate history of standard wound therapy (binary and the number of HBO services)	✓	
Cost		
Expenditures for HBO services (facility and physician supervision)	✓	✓
Expenditures for HBO and standard wound therapy	✓	
Total Medicare fee-for-service expenditures	✓	✓
Domain 2: Quality of care		
Quality		
Receipt of HBO with physician supervision (proportion of HBO services with physician supervision)	✓	✓
Adverse outcomes		
Emergency room visit (binary and number of visits)	✓	✓
Emergency room visit for treatment of diabetic lower extremity wound (binary and number of visits)	✓	
Unplanned hospital admission (binary and number of admissions)	✓	✓
Unplanned hospital admission for treatment of diabetic lower extremity wound (binary and number of visits)	✓	
Amputation of lower extremity	✓	
Death	✓	✓
Domain 5: Improper payment and claims denials		
Denied claims		
HBO claim denial (proportion of HBO claims denied)	✓	✓

Note: Domains 3 and 4 are addressed through the qualitative data collection and analysis tasks.

To determine what constitutes "appropriate history of other treatments" for individuals with diabetic lower extremity wounds, we (1) conducted a literature review, (2) consulted with physicians at Mathematica, (3) consulted with physicians who specialize in undersea and hyperbaric medicine, and (4) physicians and other representatives from Novitas, the MAC for New Jersey. The Medicare NCD for HBO requires 30 days of standard wound therapy prior to HBO, and specifies seven components of standard wound therapy (CMS 2006):

1. Debridement to remove devitalized tissue
2. Maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings
3. Assessment of vascular status and correction of any vascular problems in the affected limb if possible
4. Optimization of nutritional status
5. Optimization of glucose control
6. Necessary treatment to resolve any infection that might be present
7. Appropriate off-loading

In managing the prior authorization process, MACs review documentation and medical records prepared by the requesting physician. In constructing our measures of appropriate standard wound therapy, we are limited to what can be determined from Medicare administrative data. While vascular optimization, surgical debridement, and glycohemoglobin tests of recent glucose control generate claim records, other measures often do not. Our primary measure of appropriate standard wound therapy therefore includes only these three services.

Other forms of standard wound therapy may or may not generate claims. Offloading of pressure from the affected foot, for example, can include the use of special equipment for casts or boots that appear in an individual's claim history, but may also involve a prescription for over-the-counter orthotics that would not necessarily result in a claim. In consultation with Mathematica physician researchers, we built lists of procedure codes for each type of treatment. We then tested a number of alternative specifications of appropriate history of standard wound therapy, using various combinations of treatments.

We used outpatient, inpatient, and carrier files to identify included standard wound therapy services. In keeping with the NCD requirement of 30 days of standard wound therapy, we required the services to be received within 30 days prior to the first instance of HBO treatment in a sequence of treatments, where the sequence was identified as a set of HBO treatments in which the gap between successive treatments was 29 days or fewer. Every HBO treatment in a sequence was considered to have the same history of standard wound therapy.

Unfortunately, despite limiting attention to standard wound treatments which are expected to generate claims, our approach had limited success in identifying histories of treatments. In our diabetic lower extremity wound sample, 1.5 percent of beneficiary quarters experienced some HBO treatment in the pre-model period. However, only 0.18 percent experienced HBO treatment as part of an episode of treatments preceded by standard wound therapy in the 30 days before the first treatment. Although some of this difference is perhaps due to providers' failure to adhere to standard wound therapy guidelines, the difference is too large to attribute fully to guideline

nonadherence. More likely, our claims-dependent definition fails to reliably capture receipt of standard wound therapy prior to HBO treatment. As a consequence, we may not be able to gauge the impact of prior authorization on the likelihood of receiving the required course of standard wound care services before starting HBO therapy.

Procedure codes used to create outcome measures

Table C.2 contains the procedure codes that we used to identify a history of standard therapy. We considered utilization of debridement, dressings, vascular optimization, medical nutrition therapy, glycohemoglobin tests, and infection treatment.

Table C.2. Codes identifying history of standard therapy[2]

Code	Description
Debridement	
11000	debride infected skin
11001	debride infected skin add-on
11042	deb subq tissue 20 sq cm/<
11043	deb musc/fascia 20 sq cm/<
11044	deb bone 20 sq cm/<
11045	deb subq tissue add-on
11046	deb musc/fascia add-on
11047	deb bone add-on
97597	rmvl devital tis 20 cm/<
97598	rmvl devital tis addl 20cm/<
97602	wound(s) care non-selective
97610	low frequency, non-contact, non-thermal ultrasound, including topical app(s)
Dressings	
A6010 - A6011	collagen based wound filler
A6021 - A6024	collagen dressing
A6025	gel sheet for dermal or epidermal app
A6154	wound pouch, each
A6196 - A6199	alginate or other fiber gelling dressing
A6203 - A6205	composite dressing
A6206 - A6208	contact layer
A6209 - A6215	foam dressing
A6234 - A6241	hydrocolloid dressing
A6242 - A6248	hydrogel dressing
A6250	skin sealants, protectants, moisturizers, ointments
A6251 - A5256	specialty absorptive dressing
A6257 - A6259	transparent film

[2] This table and the one that follows include the code descriptions as they are found in CMS documentation available at https://www.cms.gov/medicare-coveraGE-database/downloads/downloadable-databases.aspx, including abbreviations and unit of measures.

Code	Description
A6260	wound cleansers
A6261	wound filler, gel/paste, per fluid ounce, not otherwise specified
A6262	wound filler, dry form, per gram, not otherwise specified
A6456	zinc paste impregnated bandage, nonelastic, knitted/woven, width greater than or equal to 3 in., and less than 5 in., per yd.
A6457	tubular dressing with or without elastic, any width, per linear yard
C1765	adhesion barrier [not covered under surgical dressings benefit]
G0168	wound closure utilizing tissue adhesive(s) only
A6209 - A6215	foam dressing
Bioengineered skin subst	
15271	app of skin subst graft to trunk, arms, legs,total wound surface area up to 100 sq cm; first 24 sq cm or less wound surface area
15272	each addtl 25 sq cm wound surface area, or part thereof
15273	app of skin subst graft to trunk, arms, legs, total wound surface area greater than 100 sq cm
15274	each addtl 100 sq cm wound surface area
15275	app of skin subst graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound area up to 100 sq cm; first 25 sq cm or less wound surface area
15276	each addtl 25 sq cm wound surface area, or part thereof
15277	app of skin subst graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound area greater than or equal to 100 sq cm; first 100 sq cm or less wound surface area
15278	each addtl 100 sq cm wound surface area
C5271 - C5278	app of low cost skin subst
C9363	skin subst
Other	
C9363	skin subst, integra meshed bilayer wound matrix, per square cm
Q4100	skin subst, not otherwise specified
Q4101	apligraf, per square cm
Q4102	oasis wound matrix, per square cm
Q4104	integra bmwd skin sub
Q4105	integra drt skin sub
Q4107	graftjacket skin sub
Q4108	integra matrix skin sub
Q4110	primatrix skin sub
Q4111	gammagraft skin sub
Q4112	cymetra allograft
Q4113	graftjacket express allograf
Q4114	integra flowable wound matri
Q4115	alloskin, per square cm
Q4116	alloderm, per square cm
Q4117	hyalomatrix, per square cm
Q4118	matristem micromatrix, 1 mg
Q4119	matristem wound matrix, per square cm
Q4120	matristem burn matrix, per square cm

Code	Description
Q4121	theraskin, per square cm
Q4131	epifix or epicord, per square cm
Q4132	grafix core, per square cm
Q4133	grafix prime, per square cm
Vascular optimization	
93925	duplex scan of lower extremity arteries or arterial bypass grafts; unilateral or limited study
93970	duplex scan of extremity veins including responses to compression and other maneuvers, complete bilateral study
93971	duplex scan of extremity veins including responses to compression and other maneuvers, limited bilateral study
93922	limited bilateral noninvasive physiologic studies of upper or lower extremity arteries, (eg, for lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus bidirectional, doppler waveform recording and analysis at 1-2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus volume plethysmography at 1-2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries with, transcutaneous oxygen tension measurement at 1-2 levels)
93923	noninvasive physiologic studies of upper or lower extremity arteries, multiple levels or with provocative functional maneuvers, complete bilateral study (eg, segmental blood pressure measurements, segmental doppler waveform analysis, segmental volume plethysmography, segmental transcutaneous oxygen tension measurements, measurements with postural provocative tests, measurements with reactive hyperemia)
93924	noninvasive physiologic studies of lower extremity arteries, at rest and following treadmill stress testing, (i.e., bidirectional doppler waveform or volume plethysmography recording and analysis at rest with ankle/brachial indices immediately after and at timed intervals following performance of a standardized protocol on a motorized treadmill plus recording of time of onset of claudication or other symptoms, maximal walking time, and time to recovery) complete bilateral
93926	duplex scan of lower extremity arteries or arterial bypass grafts; unilateral or limited study
73725	mra angio lower extremity
76881	ultrasound, extremity, nonvascular, real-time with image documentation complete
76882	limited, anatomic specific
75710	angiography, extremity, unilateral, radiological supervision and interpretation
75716	angiography, extremity, bilateral, radiological supervision and interpretation
C8912	magnetic resonance angiography without contrast lower extremity
C8913	with contrast
C8914	with and without contrast
Revascularization	
37220	revasc, endovasc, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal angioplasty
37221	revasc, endovasc, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37222	revasc, endovasc, open or percutaneous, iliac artery, each addtl ipsilateral iliac vessel; with transluminal angioplasty (list separately in addition to code for primary procedure)
37223	revasc, endovasc, open or percutaneous, iliac artery, each addtl ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (list separately in addition to code for primary procedure)
37224	revasc, endovasc, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty
37225	revasc, endovasc, open or percutaneous, femoral, popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed
37226	revasc, endovasc, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37227	revasc, endovasc, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and includes angioplasty within the same vessel, when performed atherectomy,

Code	Description
37228	revasc, endovasc, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty
37229	revasc, endovasc, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty the same vessel, when performed within
37230	revasc, endovasc, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s), angioplasty within the same vessel, when performed includes
37231	revasc, endovasc, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed
37232	revasc, endovasc, open or percutaneous, tibial/peroneal artery, unilateral, each addtl vessel; with transluminal angioplasty separately in addition to code for primary procedure)(list
37233	revasc, endovasc, open or percutaneous, tibial/peroneal artery, unilateral, each addtl vessel; with atherectomy, includes angioplasty within the same vessel, when performed
37234	revasc, endovasc, open or percutaneous, tibial/peroneal artery, unilateral, each addtl vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed
37235	revasc, endovasc, open or percutaneous, tibial/peroneal artery, unilateral, each addtl vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed (list separately in addition to code for primary procedure)
37238	transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein
37239	each addtl vein (addtl to 37238)
35450	transluminal balloon angioplasty, open; renal or other visceral artery
35452	Aortic
35458	brachiocephalic trunk or branches, each vessel
35460	Venous
35471	transluminal balloon angioplasty, percutaneous; renal or other visceral artery
35472	Aortic
35475	brachiocephalic trunk or branches, each vessel
35476	transluminal balloon angioplasty, percutaneous; venous
Bypass	
35521	axillary femoral
35533	axillary femoral femoral
35654	axillary femoral femoral
35623	axillary popliteal
35623	axillary tibial
35556	femoral popliteal
35572	femoral popliteal
35656	femoral popliteal
35558	femoral femoral
35661	femoral femoral
35566	femoral tibial
35666	femoral tibial
35566	femoral peroneal
35570	peroneal tibial
35571	popliteal peroneal
35671	popliteal peroneal
35570	tibial/peroneal trunk tibial

Code	Description
35583	femoral popliteal
35585	femoral tibial or femoral peroneal
35587	femoral peroneal or popliteal peroneal
35548	ventricular restoration
35531	under vein bypass graft procedures
35541	artery bypass graft
35546	artery bypass graft
35549	bypass graft, with vein; aortoiliofemoral, bilateral
35551	bypass graft, with vein; aortofemoral-popliteal
35563, 35565	under vein bypass graft procedures
35621, 35646, 35647, 35654	under bypass graft procedures other than vein
35651	bypass graft, with other than vein; aortofemoral-popliteal
35656 - 35671	bypass graft procedures other than vein
Endarterectomy	
35301	under thromboendarterectomy procedures on arteries and veins
35302	superficial femoral artery
35303	popliteal artery
35304	tibioperoneal trunk artery
35305	tibial or peroneal artery, initial vessel
35306	each addtl tibial or peroneal artery
35311	subclavian, innominate, by thoracic incision
35321	auxiliary-brachial
35331	abdominal aorta
35341	mesenteric, celiac, or renal
35351	Iliac
35361	Iliofemoral
35363	combined aortioiliofemoral
35371	common femoral
35372	Deep
35390	reoperation, carotid, thrombioendarterectomy, more than 1 month after original operation
Medical nutrition therapy	
97802	medical nutrition therapy; initial assessment and intervention, indiv, face to-face with the patient, each 15 minutes
97803	reassess and intervention, indiv, face-to- face with the patient, each 15 minutes
97804	group (2 or more indiv(s)), each 30 minutes
G0270	mnt reassess and subsequent intervention(s) for change in diagnosis, indiv, each 15 minutes
G0271	mnt reassess and subsequent intervention(s) for change in diagnosis, group (2 or more), each 30 minutes
Glycohemoglobin test	
83036	hba1c test
83037	hemoglobin; glycosylated (a1c) by device cleared by fda for home use
3044F	most recent hba1c level < 7.0%

Code	Description
3045F	most recent hba1c level 7.0-9.0%
3046F	most recent hba1c > 9.0% (poor control)
Infection treatment	
G8710	patient prescribed or dispensed antibiotic
G8711	prescribed or dispensed antibiotic
G9286	antibiotic regimen prescribed within 10 days after onset of symptoms
G9315	documentation amoxicillin, with or without clavulanate, prescribed as a first line antibiotic at the time of diagnosis
G9498	antibiotic regimen prescribed
J0120	injection, tetracycline, up to 250 mg
J0278	injection, amikacin sulfate, 100 mg
J0295	injection, ampicillin sodium/sulbactam sodium, per 1.5 gm
J0456	injection, azithromycin, 500 mg
J0558	injection, penicillin g benzathine and penicillin g procaine, 100,000 units
J0561	injection, penicillin g benzathine, 100,000 units
J0690	injection, cefazolin sodium, 500 mg
J0692	injection, cefepime hydrochloride, 500 mg
J0694	injection, cefoxitin sodium, 1 gm
J0695	injection, ceftolozane 50 mg and tazobactam 25 mg
J0696	injection, ceftriaxone sodium, per 250 mg
J0697	injection, sterile cefuroxime sodium, per 750 mg
J0698	injection, cefotaxime sodium, per gm
J0706	Ciprofloxacin
J0712	injection, ceftaroline fosamil, 10 mg
J0713	injection, ceftazidime, per 500 mg
J0714	injection, ceftazidime and avibactam, 0.5 g/0.125 g
J0715	injection, ceftizoxime sodium, per 500 mg
J0720	injection, chloramphenicol sodium succinate, up to 1 gm
J0743	injection, cilastatin sodium; imipenem, per 250 mg
J0744	injection, ciprofloxacin for intravenous infusion, 200 mg
J0875	injection, dalbavancin, 5 mg
J0878	injection, daptomycin, 1 mg
J1267	injection, doripenem, 10 mg
J1335	injection, ertapenem sodium, 500 mg
J1364	injection, erythromycin lactobionate, per 500 mg
J1580	injection, garamycin, gentamicin, up to 80 mg
J1590	injection, gatifloxacin, 10 mg
J1840	injection, kanamycin sulfate, up to 500 mg
J1850	injection, kanamycin sulfate, up to 75 mg
J1956	injection, levofloxacin, 250 mg
J2010	injection, lincomycin hcl, up to 300 mg
J2020	injection, linezolid, 200 mg

Code	Description
J2185	injection, meropenem, 100 mg
J2265	injection, minocycline hydrochloride, 1 mg
J2280	injection, moxifloxacin, 100 mg
J2407	injection, oritavancin, 10 mg
J2460	injection, oxytetracycline hcl, up to 50 mg
J2510	injection, penicillin g procaine, aqueous, up to 600,000 units
J2540	injection, penicillin g potassium, up to 600,000 units
J2543	injection, piperacillin sodium/tazobactam sodium, 1 gram/0.125 grams (1.125 grams)
J2770	injection, quinupristin/dalfopristin, 500 mg (150/350)
J3000	injection, streptomycin, up to 1 gm
J3090	injection, tedizolid phosphate, 1 mg
J3095	injection, telavancin, 10 mg
J3243	injection, tigecycline, 1 mg
J3260	injection, tobramycin sulfate, up to 80 mg
J3370	injection, vancomycin hcl, 500 mg
J7682	tobramycin, inhalation solution, fda-approved final product, non-compounded, unit dose form, administered through dme, per 300 milligrams
J7685	tobramycin, inhalation solution, compounded product, administered through dme, unit dose form, per 300 milligrams
S9497	iv antibiotic every 3 hours
S9500	iv antibiotic every 24 hours
S9501	iv antibiotic every 12 hours
S9502	iv antibiotic every 8 hours
S9503	iv antibiotic every 6 hours
S9504	iv antibiotic every 4 hours
Q0144	azithromycin, dehydrate
S9494	hit antibiotic total diem
G8709	med reas antibiotic pres
G9558	tx beta-lactam abx therapy
G9505	abx pres w/in 10 dys of symp
G8916	pt w iv ab given on time
G8918	pt w/o preop order iv ab pro
87040	culture, blood
87070	culture, any other source except urine, blood or stool
87071	quantitative, aerobic with isolation and presumptive identification of isolates, any source except urine, blood, or stool
87073	quantitative, anaerobic with isolation and presumptive identification of isolates, any source except urine, blood, or stool
87075	any source, except blood, anaerobic with isolation and presumptive identification of isolates
87076	anaerobic isolate, addtl methods required for definitive identification, each isolate
87077, 87140, 87143, 87147	culture, aerobic bacteria
87088	aerobic isolate, addtl methods required for definitive identification, each isolate
87081	culture, presumptive, pathogenic organisms, screening only
87084	with colony estimation from density chart

We identified codes for amputation of the lower extremity in the same way we identified standard wound therapy services (see Table C.3), through literature review and in consultation with Mathematica, industry, and Novitas physicians. We limited attention to amputation below the knee or lower on the leg, to capture the procedures most often performed on patients with diabetic lower extremity wounds.

Table C.3. Codes identifying lower leg amputation

CPT Code	Description
27880	Amputation, leg, through tibia and fibula;
27881	Amputation, leg, through tibia and fibula; with immediate fitting technique
27882	Amputation, leg, through tibia and fibula; open, circular (guillotine)
27884	Amputation, leg, through tibia and fibula; secondary closure or scar revision
27886	Amputation, leg, through tibia and fibula; re-amputation
27888	Amputation, ankle, through malleoli of tibia and fibula (eg, Syme, Pirogoff type
27889	Ankle disarticulation
28800	Amputation, foot; midtarsal (eg, Chopart type procedure)
28805	Amputation, transmetatarsal
28810	Metatarsal with toe, single
28820	Metatarsophalangeal joint
28825	Interphalangeal joint

Methods for descriptive figures

One consequence of our sample selection approach—that is, retaining beneficiaries in the sample from the date of their diagnosis until exit through death, moving, or leaving FFS Medicare—is that the health characteristics of the study population change over time: only beneficiaries with active conditions appear in the early quarters, as their diagnoses draw them into the population. Beneficiaries with new diagnoses are added over time, but beneficiaries whose conditions first appeared in 2012 or 2013 stay in the sample, possibly for several years after their conditions resolve. Utilization and expenditure patterns therefore change over time, as the proportion of the population actively experiencing one of the included medical conditions decreases.

Although our DID approach (described below) controls for this trend in the population, we took steps to remove the trend from our descriptive analysis figures. The change in prevalence of active medical conditions over time makes it difficult to visually detect departures from the trend in figures. We therefore developed figures showing trends in utilization and expenditures[3], limiting each individual's contribution to the sample to the four quarters following his or her date of diagnosis. While it is important to observe outcomes over time (especially for adverse events), observing individuals in just the year following their diagnosis allows us to capture HBO utilization and expenditures at the time they are most likely incurred, and gives us a comparable

[3] These are presented in Chapter IV, Quantitative Analysis Results

population in each quarter of individuals who were diagnosed in the previous year. The vast majority of beneficiaries who receive HBO have their first treatment within one year of the first time a diagnosis for an included condition appears in their claim record.

Regression methods

The main model is as follows:

Equation 1

$$E[Y_{ist}] = F(\alpha + \sum_{s \in S_{-1}} \rho_s I_s + \sum_{t \in T_{-1}} \gamma_t I_t + \beta D_{st} + \boldsymbol{\delta X_{ist}})$$

where Y_{ist} is the outcome for beneficiary *i* in state *s* in quarter *t*; I_s and I_t are state and quarter fixed effects, respectively (omitting one indicator from each group); D_{st} takes value 1 in states and quarters when the model was in effect, and 0 otherwise; and $\boldsymbol{X_{ist}}$ is a set of beneficiary-quarter–level control variables. Controls include age, age squared, HCC (Hierarchical Condition Categories) score, and indicators for race (white, black, or other), sex, rural residence, dual eligibility for Medicare and Medicaid, and each of the study's included conditions.[4] The coefficient of interest is β, which gives the estimated per-beneficiary per-quarter impact of residing in a treatment state after the prior authorization model was implemented. *F(x)* is a function that determines whether the regression model is logistic (binary outcomes, such as the probability of HBO utilization), negative binomial (count outcomes, such as the number of emergency department visits), or OLS (continuous outcomes, such as expenditures). For ease of interpretation, we converted logistic and negative binomial regression coefficients into average marginal effects.

We also estimated a model allowing prior authorization to have different effects in each model state. The effects of the model might vary by state because of characteristics such as availability of HBO facilities, local practice patterns, and MAC practices, among others. The state-specific model specification resembles Equation 1, except that there are three β terms, one for each state.

Finally, to gauge the sensitivity of our results, we estimated a model allowing for the possibility that the model's effects changed over time after implementation. This could have happened if there had been a ramp-up period before MACs fully implemented the prior authorization model, or if it took some time for providers to become accustomed to strict adherence to pre-existing documentation requirements enforced under the model. The flexible post-period model specification also resembles Equation 1, except that each sequential quarter after the model went into effect has its own β term. We identify quarters after implementation, accounting for the fact that Michigan began requiring prior authorization for HBO before Illinois

[4] Indicators for the conditions were included in the regressions for the entire population of beneficiaries with any included condition. Regressions using only the group of beneficiaries with diabetic lower extremity wounds excluded the condition indicators.

and New Jersey did. Therefore, the first quarter after implementation is quarter 14 for Michigan but quarter 15 for Illinois and New Jersey.[5]

[5] For this model and the two previous ones, we tested two different versions of the start date in Illinois and New Jersey. Since the model went into effect on August 1, 2015, which is a full month into quarter 15 of our study period, we conducted analyses designating quarter 15 as the first treatment quarter for these states, and a second set of analyses designating quarter 15 as the last pre-treatment quarter. Results were similar across these specifications.

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

APPENDIX D

HBO BENEFICIARY WEIGHTING

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

This appendix describes the approach we used to balance the model and comparison state data in the study and the results from this approach. It is divided into three sections that are presented below:

- Defining included beneficiaries and examining covariate balance
- Propensity score weighting approach
- Choice of adjustment approach

We discuss each subsection below.

A. Defining included beneficiaries and examining covariate balance

To be included in the study, a beneficiary had to reside in one of the model states (Illinois, Michigan, or New Jersey) or in one of the comparison states in the same MACs (Delaware, District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, Virginia [selected areas], or Wisconsin). In addition, beneficiaries had to have at least one inpatient or two outpatient visits related to one of the following diagnoses: diabetic ulcers of the lower extremities, osteomyelitis, soft tissue radionecrosis, osteoradionecrosis, or actinomycosis. Additionally, included beneficiaries must not have been diagnosed with these conditions prior to 2013. Table D.1 shows the resulting number of beneficiaries included in the model and comparison states.

Table D.1. Number of beneficiaries based on initial inclusion criteria

	Model states	Matched-comparison states
2012	23,910	25,824
2013	39,620	42,119
2014	51,191	54,078
2015	61,978	65,656
2016	68,317	71,855

Note: The numbers increase each year because beneficiaries who continue to be alive are included in all subsequent quarters after the quarter they are initially identified for inclusion. Thus, all beneficiaries identified in 2012 who are alive in 2013 are also included in the 2013 numbers, etc. The model states included: Illinois, Michigan, or New Jersey. The comparison states included: Delaware, District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, Virginia [selected areas], or Wisconsin.

After obtaining the sample of beneficiaries, we examined the initial balance between the model and comparison beneficiaries within each quarter along a set of key characteristics: age, rural location, gender, race, and the percentage with each of the diagnoses noted above. In general, we found only modest differences in the characteristics of beneficiaries in the model and comparison state samples. On average across all 20 observed quarters, about 82 percent of beneficiaries in the model state sample had diabetic ulcers of the lower extremities, compared with about 83 percent for beneficiaries in the comparison state sample whereas about 77 percent of model state sample beneficiaries were white compared with 82 percent for comparison state sample beneficiaries. We found very small differences for the percentages for female and those with the other four diagnoses besides diabetic ulcers of the lower extremities. However, we did find a somewhat large difference in the percent of beneficiaries in model states who lived in rural

areas, at 13 percent, compared with about 24 percent in comparison states. We present all of these differences, across all 20 quarters, in Figures D.1 through D.5.

B. Propensity score weighting approach

To adjust for the cited differences above, we used an inverse propensity score weighting approach, which involves two steps.[6] First, for each quarter of data, we estimated a logistic regression, predicting treatment status (living in a model or a comparison state) based on the following set of characteristics: beneficiary age; whether the person lived in a rural area; gender; race (separate indicators for black, white, Hispanic, or other); and indicators for whether the beneficiary had diabetic ulcers of the lower extremities, osteomyelitis, soft tissue radionecrosis, osteoradionecrosis, or actinomycosis. These regressions provided predicted probabilities for each beneficiary, which represent the likelihood that the beneficiary resides in a state with prior authorization (Rosenbaum and Rubin 1983). Each model was run using a single quarter of data for a single MAC; the resulting propensity score weights therefore balance the model and comparison beneficiaries in each quarter within each MAC and for the combination of all MACs. The second stage of this process was calculating weights, ω, for each beneficiary, defined as

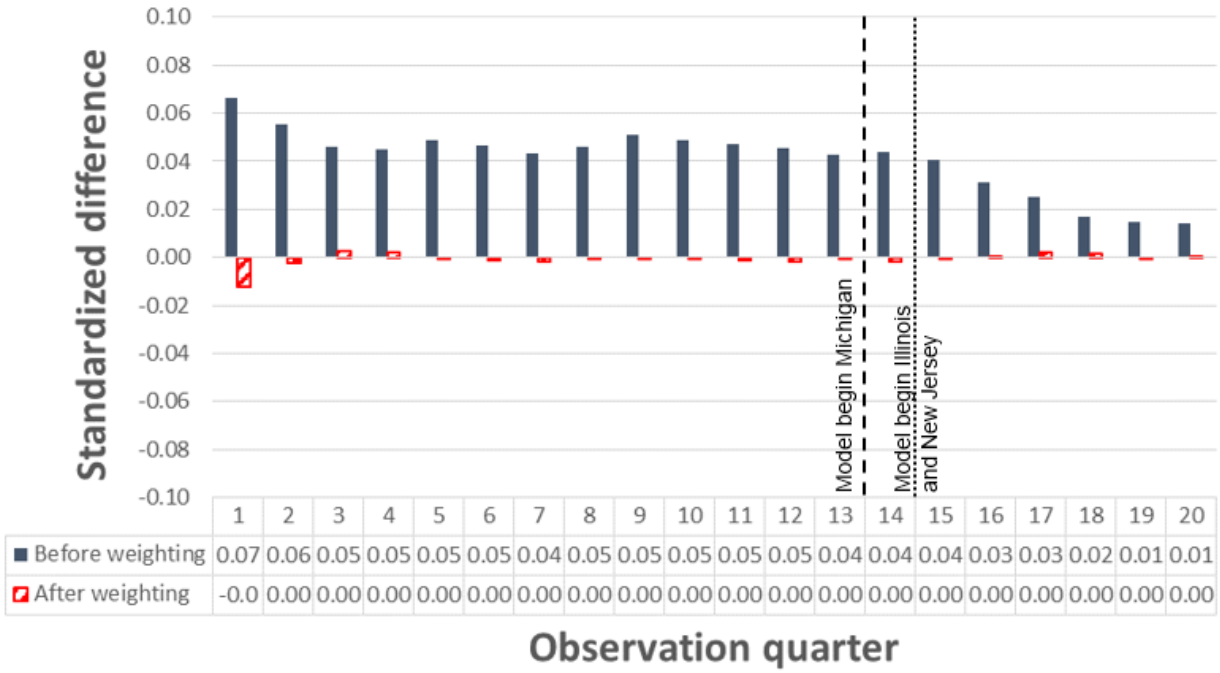
$$\omega(W, x) = W + (1 - W)\frac{\hat{e}(x)}{1 - \hat{e}(x)}$$

where $W = 1$ if a beneficiary lived in a model state and $W = 0$ if a beneficiary lived in a comparison state, x represents the set of characteristics included in the propensity score model, and $\hat{e}(x)$ represents the estimated propensity score (Guo and Fraser 2009). These propensity score weights reduce to 1 for beneficiaries living in model states and $\frac{\hat{e}(x)}{1 - \hat{e}(x)}$ for beneficiaries living in comparison states. As shown by the following figures, the analysis weights were highly effective in reducing imbalance on the key characteristics.

In Figures D.1 through D.5, we show for each quarter observed the standardized differences on key characteristics between the beneficiaries in the model states and those in the comparison states, prior to any weighting (in dark blue) and after the propensity score adjusted analysis weight is applied (in red). The vertical bars demonstrate the size of the differences before and after the calibrations. Each figure also includes a data table with the numeric values for the standardized differences. Table D.1 presents the yearly percentage averages of each characteristic before and after the weights are applied. The table and figures show a consistently effective reduction and near elimination of any imbalance on the key characteristics.

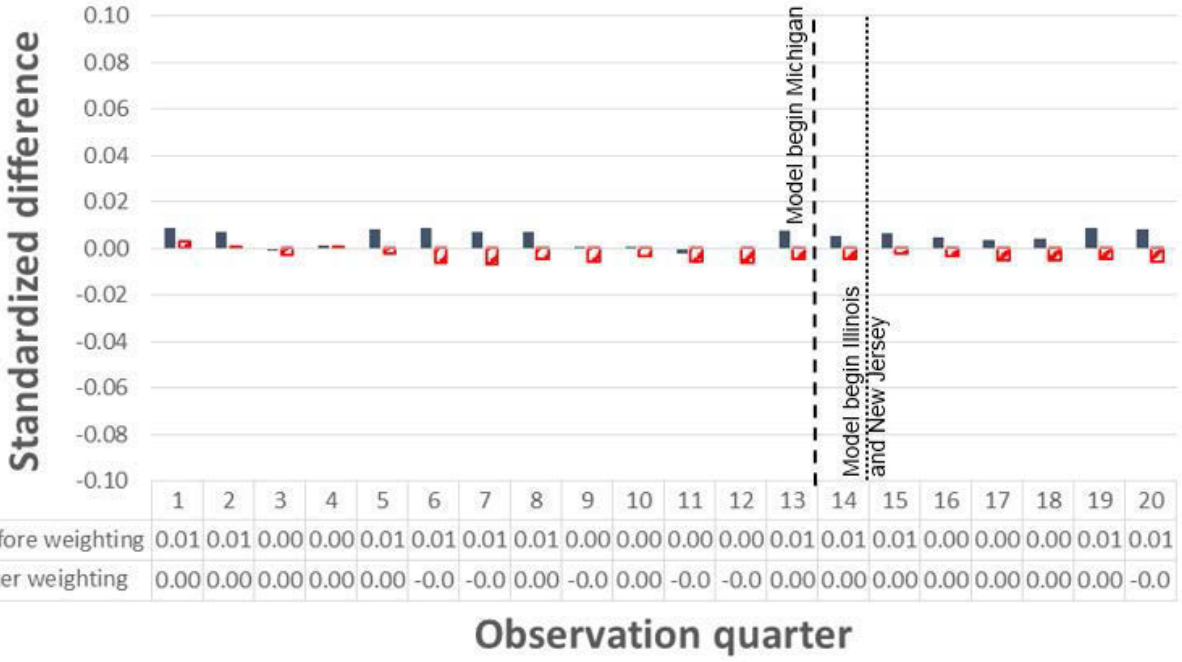
[6] We initially tried an optimal matching approach that involved calculating distances between each treatment and comparison beneficiary and then matching comparison beneficiaries to intervention beneficiaries with the smallest distance between them. However, we were unable to achieve desired balance in all quarters without dropping some model state beneficiaries from the analysis file. In addition, several simplifications of the matching procedure were needed to make the problem computationally feasible, including matching on stratified versions of the propensity score. Therefore, matching did not present a viable option for balancing the model and comparison state beneficiaries.

Figure D.1. Beneficiary balance, percent with diabetic ulcers of the lower extremities, before and after propensity score adjustments



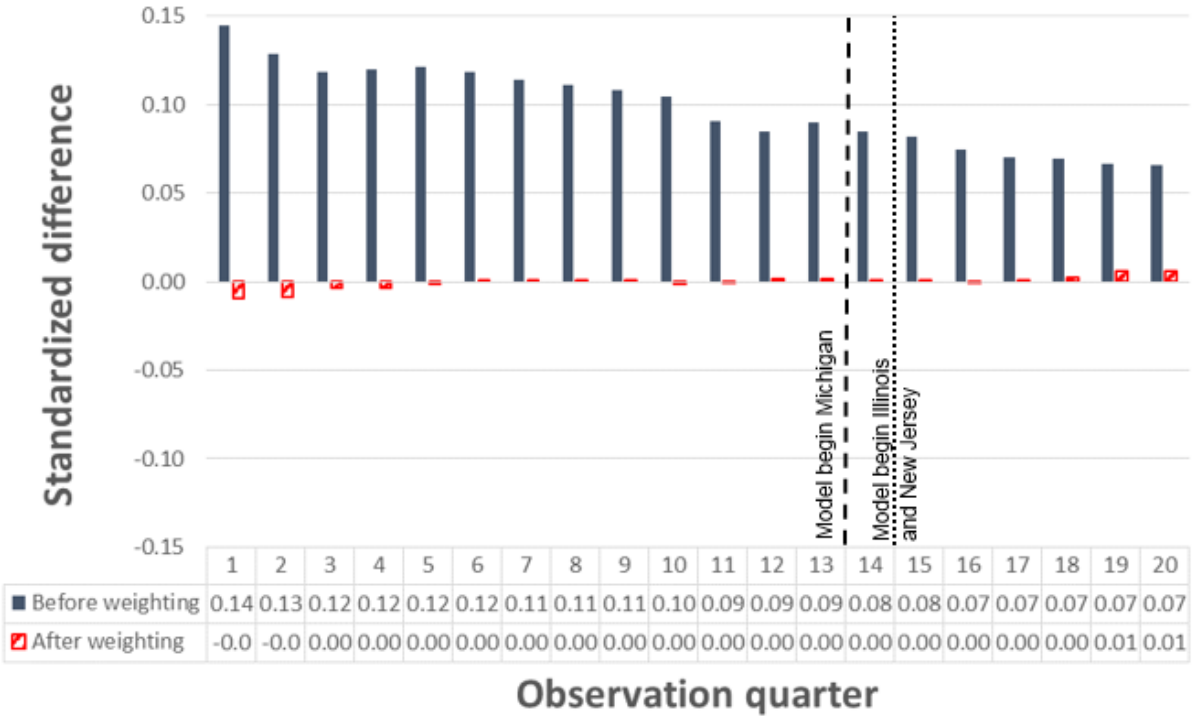
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Before weighting	0.07	0.06	0.05	0.05	0.05	0.05	0.04	0.05	0.05	0.05	0.05	0.05	0.04	0.04	0.04	0.03	0.03	0.02	0.01	0.01
After weighting	-0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

Figure D.2. Beneficiary balance, percent female, before and after propensity score adjustments



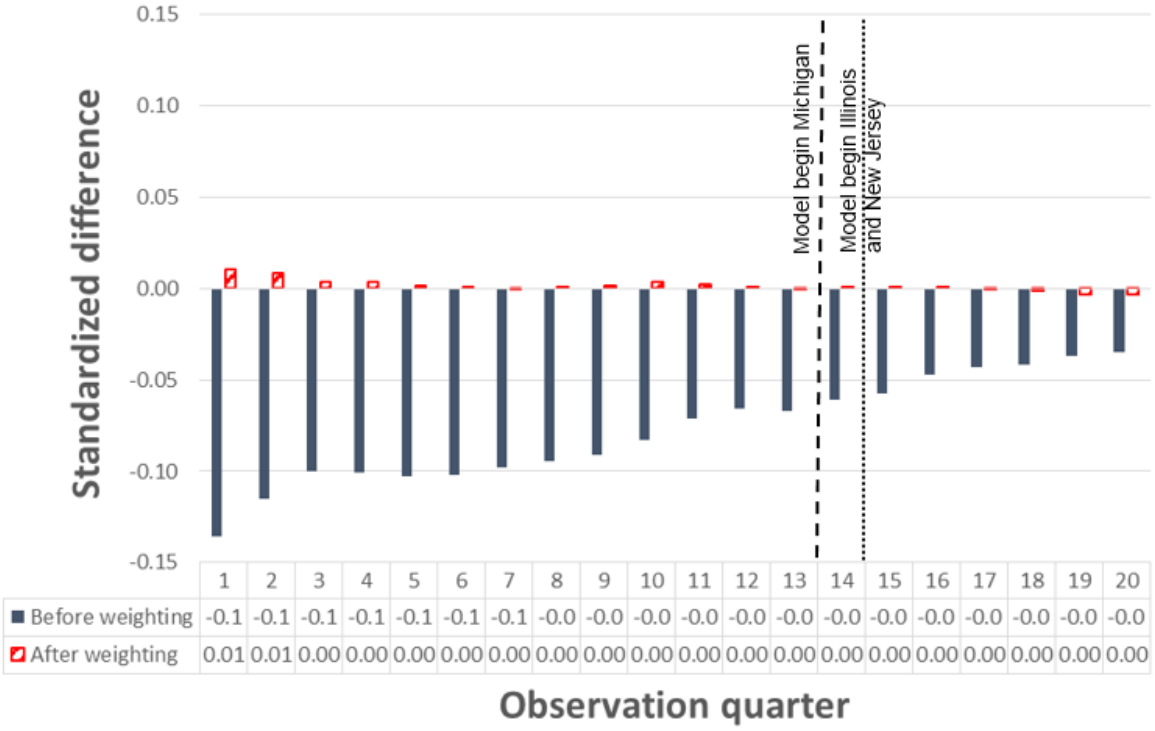
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Before weighting	0.01	0.01	0.00	0.00	0.01	0.01	0.01	0.01	0.00	0.00	0.00	0.00	0.01	0.01	0.01	0.00	0.00	0.00	0.01	0.01
After weighting	0.00	0.00	0.00	0.00	0.00	-0.0	-0.0	0.00	-0.0	0.00	-0.0	-0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-0.0

Figure D.3. Beneficiary balance, percent white, before and after propensity score adjustments



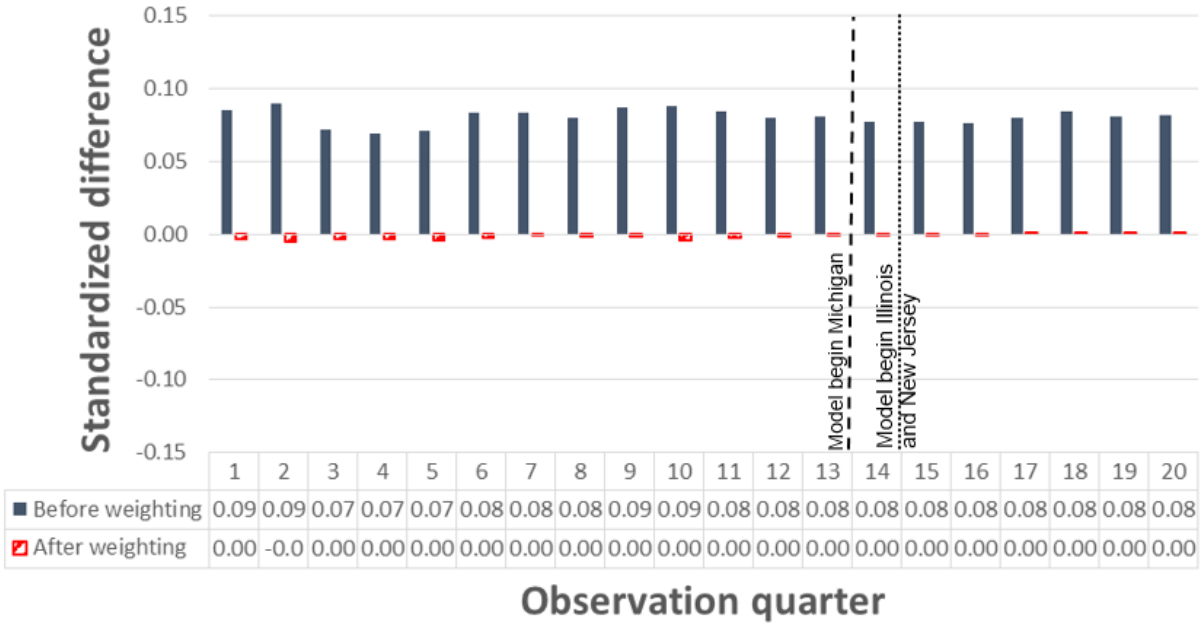
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Before weighting	0.14	0.13	0.12	0.12	0.12	0.12	0.11	0.11	0.11	0.10	0.09	0.09	0.09	0.08	0.08	0.07	0.07	0.07	0.07	0.07
After weighting	-0.0	-0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.01	0.01

Figure D.4. Beneficiary balance, percent black, before and after propensity score adjustments



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Before weighting	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.0	-0.0	-0.0	-0.0	-0.0	-0.0	-0.0	-0.0	-0.0	-0.0	-0.0	-0.0	-0.0
After weighting	0.01	0.01	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

Figure D.5. Beneficiary balance, percent rural, before and after propensity score adjustments



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Before weighting	0.09	0.09	0.07	0.07	0.07	0.08	0.08	0.08	0.09	0.09	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.08
After weighting	0.00	-0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

Table D.2. Percent average yearly beneficiary characteristics before and after propensity score weighting

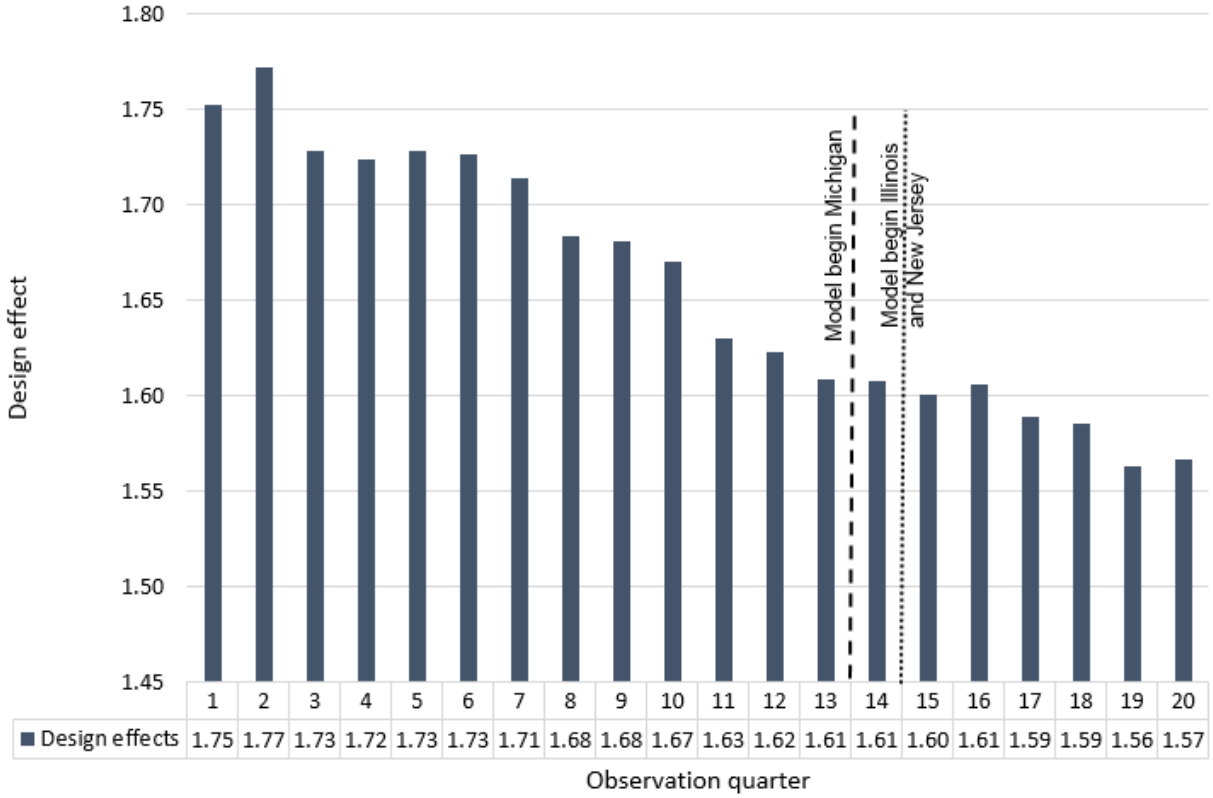
	2012			2013			2014			2015			2016		
	Model	Comparison		Model	Comparison		Model	Comparison		Model	Comparison		Model	Comparison	
Characteristic		Before	After		Before	After		Before	After		Before	After		Before	After
Rural	13.0	24.1	12.9	13.1	24.3	13.0	13.0	24.7	13.0	13.1	24.6	13.1	13.3	24.7	13.3
Female	42.0	42.6	41.9	42.6	42.9	42.3	43.1	43.1	42.9	43.2	43.3	43.0	43.6	43.6	43.3
Race															
White	75.9	82.2	75.8	76.4	81.9	76.4	76.6	81.4	76.6	76.8	81.2	76.8	77.5	81.4	77.6
Black	19.6	14.6	19.8	19.1	14.9	19.1	18.7	15.1	18.7	18.1	15.2	18.1	17.2	14.9	17.2
With diabetic ulcers of the lower extremities	81.1	82.8	80.9	81.8	83.2	81.8	81.8	82.9	81.8	81.9	82.6	81.9	81.4	81.4	81.4

Note: The model states included: Illinois, Michigan, and New Jersey. The comparison states included: Delaware, District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, Wisconsin, and Virginia (Arlington and Fairfax counties, city of Alexandria). Yearly averages were calculated as the unweighted average of the percent of each characteristic across all quarters in a given year.

C. Choice of adjustment approach – matching vs. weighting

A common approach to reduce or eliminate imbalance between an intervention and comparison sample is to select a subset of the possible comparison units and then matching them to treated units, often through using a propensity score. We initially considered such an approach but rejected it in favor of a propensity score weighting approach, which performed better and was more flexible than the matching approach we used. In order to achieve balance on key characteristics, individual matches must have low distance on each characteristic. However, in this analysis, we found that balancing on certain characteristics, particularly urban/rural and whether beneficiaries had diabetes of the lower extremities, resulted in worse balance on other characteristics or treatment beneficiaries without any viable match. We used several strategies to address this problem, including the use of squared and interaction terms in the propensity score model, calipers of differing lengths, varying matching ratios, and matching within certain strata of the propensity score. None resulted in a satisfactory matched comparison set. The propensity score weighting approach, on the other hand, is more flexible, in that weights are used to balance the treatment and comparison samples on the range of characteristics. The full range of available comparison beneficiaries is used as the counterfactual, rather than a selected subset, so even if a particular comparison beneficiary is not a perfect match to any treatment beneficiary, they may still contribute to improve balance between the full comparison and treatment groups. However, we had to examine the design effect caused by differential weights to ensure that the weights did not substantially increase the standard errors of our estimates. We show the design effects due to weighting in Figure D.6.

Figure D.6. Design effects of propensity score weights, by quarter



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Design effects	1.75	1.77	1.73	1.72	1.73	1.73	1.71	1.68	1.68	1.67	1.63	1.62	1.61	1.61	1.60	1.61	1.59	1.59	1.56	1.57

The design effect due to weighting is a measure of the increase in the variance of an outcome measure induced by weights. It is scaled to a simple random sample (SRS), which has no differential weights and therefore no design effect. Therefore, a design effect of 1.0 indicates no increase in variance due to weighting, whereas a design effect of 1.5 indicates a 50 percent increase in variance attributable to weighting. The propensity score weights had design effects of ranging from about 1.57 to 1.77 across all quarters, making the variance of the outcomes about 60 to 70 percent higher than an analysis without weights. Given the very large available sample sizes, we do not consider this design effect as a substantial reduction in the statistical power of our analyses, as shown in Appendices G and H.

APPENDIX E

QUALITATIVE DATA COLLECTION AND CODING

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

Appendix E details the qualitative data collection and coding activities we performed.

Table E.1 presents each of the research questions that guided our data collection efforts, and identifies the stakeholders we obtain information from as well as the data collection methods we used.

Table E.1. Research questions and relevant stakeholders, by data collection approach

Research questions	MAC Interviews	Site visits and interviews
How does the prior authorization model affect Medicare use and cost? Was the model cost effective for the Medicare program?	M	SP
How does a prior authorization model affect the quality of care and access to care?		SP, B
How does a prior authorization model affect Medicare program operations?	M	
How does a prior authorization model affect provider behavior and satisfaction?		SP
How feasible is expanded/national prior authorization for HBO services?	M	SP

M = MACs; SP = HBO providers (staff and physicians); B = HBO Medicare beneficiaries.

Data collection and analysis activities included telephone interviews with MAC personnel; HBO stakeholder interviews, including in-person structured interviews with facility staff conducted as a part of site visits with HBO facilities in the model states and additional telephone interviews with the HBO facility staff and beneficiaries or their caregivers; coding and analysis of each of these interviews; an online survey of HBO facilities in model states; and a structured in-person interview with three CPI senior staff. Each of these activities are discussed in the sections that follow. At the end of this appendix, we present the interview protocols that were used to guide the interviews we performed. All recorded interviews and all transcripts were stored securely on SharePoint within the protected Mathematica network.

MAC interviews

Mathematica, in partnership with PRI, conducted in-depth telephone interviews with personnel from three MACs administering the model in Illinois, Michigan, and New Jersey. These MACs are Wisconsin Physicians Service Insurance Corporation (WPS), Novitas Solutions (Novitas), and National Government Services Inc. (NGS). These interviews occurred in August 2016, approximately 16 months after model launch in Michigan and 12 months after model launch in New Jersey and Illinois. Table E.2 shows the number of telephone interviews completed with staff from each MAC, as well as the total number of staff interviewed and their different roles at their respective MAC.

Table E.2. MAC interviews

MAC	State	Role of personnel interviewed	Number of interviews	Number of staff interviewed*	Interview Dates
NGS	Illinois	Supervisory/management staff; Medical reviewer staff	1	2	August 22, 2016
WPS	Michigan	Supervisory/management staff; Medical reviewer staff	1	5	August 22, 2016
Novitas	New Jersey	Supervisory/management staff; Medical reviewer staff	4	4	August 19–23, 2016
Totals			**6**	**11**	

*In some cases, multiple staff were interviewed at the same time.

MACs are responsible for conducting medical necessity reviews, making and issuing notifications of affirmative or non-affirmative prior authorization determinations, and reviewing, paying, or denying claims for HBO therapy, as well as other services. PRI conducted semi-structured, in-depth telephone interviews with PAR reviewers, supervisors, and managers from Wisconsin Physicians Service Insurance Corporation (WPS), Novitas Solutions (Novitas), and National Government Services Inc. (NGS) to collect a baseline description of (1) the model ramp-up and early implementation activities, (2) MAC-specific procedures for processing HBO PARs, and (3) HBO provider outreach and education efforts. In addition, we sought to obtain respondents' perspectives on (4) the model's initial effects on HBO provider billing behavior and (5) preliminary lessons learned and best practices.

PRI developed a semi-structured interview guide for MAC staff that included 26 questions organized by a focus on operations, supplier behavior, or prior authorization review processes. After sending a letter to the model project management teams at each MAC to request their participation in this CMS-sponsored evaluation, PRI worked with MACs to identify appropriate staff and schedule interviews. PRI distributed the interview guide to MACs in advance, allowing MAC staff to reflect on the questions before the interview. Interviews were recorded (with participant permission) and then transcribed for coding and analysis. In some cases, multiple staff were interviewed together, during a single phone call. This was done at the request of the MACs, only after the research team determined that group interviews would not unduly influence the content or candor of the feedback we received.[7]

HBO stakeholder interviews, including facility staff, beneficiary, and caregiver interviews

During the second year of the evaluation, Mathematica, in partnership with PRI, conducted two site visits per state (six total) to outpatient HBO facilities in model states to explore facility staff and beneficiaries' perceptions of and experiences with the prior authorization model. During the site visits, the evaluation team conducted pre-scheduled thirty minute interviews with HBO facility staff – specifically administrators, nurses, technicians, and referring and treating

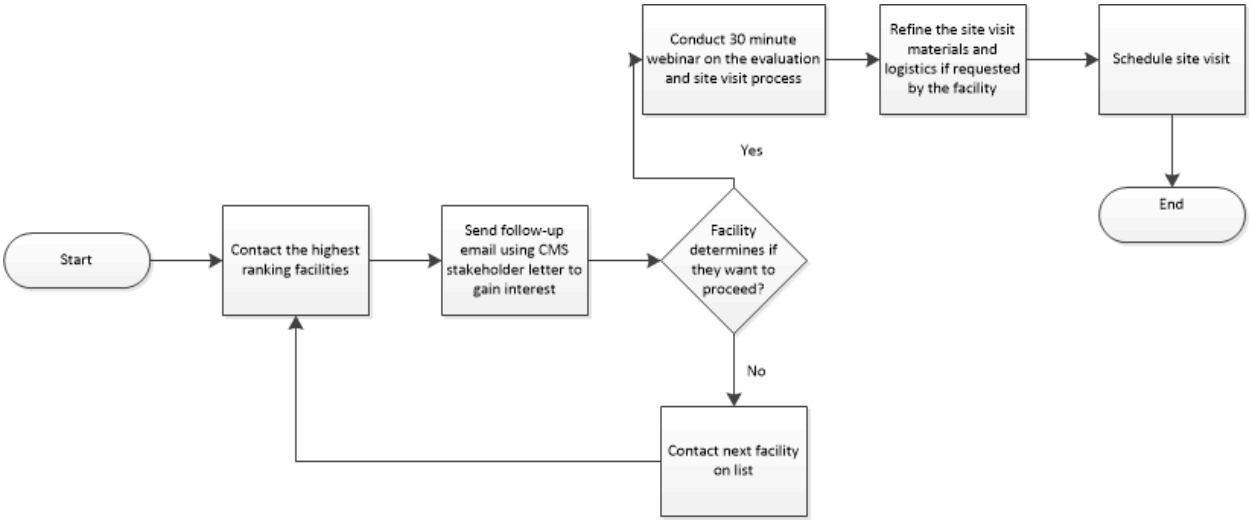
[7] The research team evaluated the rank of the individuals being interviewed together, to avoid situations where managers and their staff participated in the same interview. In addition, the interviewer was attentive to gathering information from all members in a group interview to make sure each interview participant shared feedback and none of them unduly influenced others in the group

physicians. Fifteen minute interviews were scheduled and conducted with beneficiaries or their caregivers. These interviews focused on understanding 1) the different roles and responsibilities of facility staff submitting prior authorization requests, 2) how these staff communicate with MACs about prior authorization documentation and approval, and 3) beneficiaries' experience with and awareness of the prior authorization process. Interviews were recorded with the permission of respondents, and each interview was conducted by two Mathematica or PRI research staff, including one who led the interview and another who served as note-taker and recorder.

Facility and beneficiary recruitment

Mathematica selected facilities for recruitment to participate in the site visits based on the volume of HBO claims submitted after model launch; visiting high volume facilities ensured the research team would have a viable number of beneficiaries to interview and that facility staff would have sufficient experience with the HBO PAR process to provide thoughtful and informed feedback. The research team used Medicare claims data to identify and rank sites within each of the three HBO prior authorization model states (Illinois, Michigan, and New Jersey) by the number of unique claims the facility submitted for one of the five conditions subject to prior authorization. The research team contacted sites in order of their rank (from highest to lowest volume of Medicare HBO claims submitted since model launch). Through this outreach the research team sought to gauge the facilities' willingness to participate in the site visits. Figure E.1 shows the Site Selection Process.

Figure E.1. HBO facility site selection process



Among the top ranking facilities, the research team attempted to recruit facilities that were managed by different HBO management companies. Ultimately, site selection was based upon a facility's responsiveness to our initial outreach, willingness to allow onsite access to the research team, approval to participate by their managing organization, and other intervening factors that prevented timely participation such as the need for some facilities to obtain internal Institutional Review Board (IRB) approval. The research team ended site recruitment when two facilities in each of the three model states agreed to participate.

Several facilities requested a formal presentation by the research team to better understand the purpose and goals of the site visits and how interviews would be scheduled and conducted. In addition, the research team provided each facility with an outreach kit that included flyers to post around the facility requesting staff participation; a Frequently Asked Questions (FAQ) document; interview consent forms to be completed by both staff and beneficiaries prior to the visit; and appointment tracking sheets and contact sheets to facilitate interview scheduling.

Facility staff sample selection

Facility staff, including physicians, were recruited to participate by the facility point of contact. This individual was often a member of the facility's administrative staff. Potential participants were contacted by the facility point of contact based on their knowledge of and involvement with the HBO prior authorization process at their facility. They were provided information about the evaluation, including a consent form that described the purpose of the study and how their information would be used. Facility staff were given the option of being interviewed in person or by telephone on the day of the site visit. If they were not available on this day, a telephone interview with the research team was scheduled with the participant for a later date.

Beneficiary interview sample selection

Once the six sites were recruited, facility staff assisted with identifying and recruiting for interviews beneficiaries who had sought HBO therapy after the prior authorization model launch.[8] An interview schedule was prepared prior to the site visit, and beneficiaries or their caregivers were interviewed at a time that was convenient for them. Beneficiaries or their caregivers were also given the option of being interviewed by telephone if that was their preference. At the discretion of each site's management, participating beneficiaries received a $20 Visa gift card from Mathematica for their participation.

We designed the onsite facility staff and beneficiary interview protocols to minimize burden on the respondent, be respectful of their time, protect their privacy, limit intrusion into staff and facility operations, and comply, when possible, with site-specific requests from the sites' HBO management companies. Table E.3 shows the number of completed on-site staff, physician, beneficiary, and caregiver interviews at the six participating HBO facilities.

[8] These included both Medicare-only and dual eligible beneficiaries.

Table E.3. Site-visits and telephone interviews[9]

Location	Date of Onsite Visit	Beneficiary	Caregiver	Physician	Staff	Totals
Hamilton, New Jersey	25-Apr-17	0	4	6	4	14
Hackensack, New Jersey	27-Apr-17	5	0	3	1	9
Harvey, Illinois	15-May-17	4	0	2	7	13
Warren, Michigan	16-May-17	3	0	1	5	9
Detroit, Michigan	17-May-17	0	0	2	5	7
Naperville, IL	25-May-17	5	0	1	4	10
Total Number of interviews		17	4	15	26	62

Coding and analysis of MAC, HBO facility staff, and beneficiary interviews

To ensure consistency and facilitate the coding and analysis of responses, the research team designed interview guides for MACs, HBO facility staff, and beneficiaries to capture experiences with the prior authorization process and any perceived effects on beneficiary access to care or quality of care. The MAC interview protocol focused on role and involvement, training and education, changes at MAC, PAR review and appeals process, feedback from providers, challenges, insights, medical necessity guidelines, changes in provider processes, effect on timeliness and quality of services, pre-payment review, recommendations, and overall satisfaction with PA. The interview protocol for facility staff focused on the PAR submission process, how HBO facility staff and physicians gather documentation for and communicated with MACs, and any perceived effects on facility operations or beneficiary care. Beneficiary interview questions focused on how the beneficiary was referred to the HBO center, their perceived exposure to and awareness of the PAR submission process, whether they understood the PAR submission and review process and the MAC's decision and its rationale, and their perceptions of their access to and quality of care. Of the 6 interviews conducted with MACs, 30 interviews conducted with facility staff, and 16 interviews conducted with beneficiaries or their caregivers, all but three were recorded and transcribed for coding and analysis, with the research team relying on the notes taken for the other three to code and analyze these interviews.

Interview transcripts were coded using NVivo qualitative analysis software and then analyzed using coding queries focused on specific evaluation research questions. These queries pulled coded comments on each question or topic from across stakeholder groups (MAC staff, facility staff, and beneficiaries), with each comment labeled with the type of stakeholder and state from which the comment came. We reviewed material for each research question from across all stakeholder groups concurrently, to identify frequently occurring themes, areas of agreement and disagreement across different stakeholder groups, and any inconsistent findings.

[9] During site visits in New Jersey, we interviewed a greater proportion of beneficiaries and caregivers who were waiting for HBO prior authorization approval than we had in the other model states, where many of the beneficiaries had already begun HBO treatment.

Mathematica developed a codebook organized around the evaluation's domains and research questions, to facilitate analysis and focus the coding team on core topics of interest. The codes are organized into three sections that correspond to the evaluation's primary sample groups:

- HBO Medicare beneficiaries
- HBO Providers (staff and physicians)
- HBO MACs

Several themes were incorporated into each section of the codebook including the prior authorization model's effects on the following:

- Healthcare utilization
- Medical necessity
- Prior authorization knowledge
- Clinical and prior authorization protocol
- Quality and access to care
- Personnel behavior and satisfaction
- Scalability/feasibility of prior authorization for HBO

Where appropriate, the codebook incorporated other aspects of the prior authorization model, including the circulation of informational outreach and resources to educate stakeholders about the prior authorization model, as well as stakeholders' challenges, insights, understanding of medical necessity guidelines, and recommendations. Throughout the coding process, we revised the codebook to account for themes appearing in interviews that were not included in the initial coding scheme but were relevant to the evaluation. The original coding team consisted of two primary and three back-up raters. We used the percentage agreement measure to run round-to-round inter-rater reliability checks (McHugh 2012). We then calculated the overall percentage agreement measure by averaging the separate measures of percentage agreement. A total of 67 beneficiary and provider interviews were coded by 3 raters, and their coding averaged to be about 93 percent in agreement.

Online survey of HBO facilities in model states

Mathematica developed and fielded a web-based survey with HBO facilities in model states to help validate the key themes that emerged from interviews and site visits. The online survey instrument was designed to take 15-minutes and was field tested from July 18, 2017 to September 18, 2017. Table E.4 provides final response rates by state.

To identify respondents for the online survey, we used weekly Center for Program Integrity (CPI) HBO prior authorization reports matched to Medicare claims data to identify facilities in model states that had documented experience with prior authorization. Since facility national provider identifiers (NPIs) appear on the CPI reports of HBO prior authorization requests, we merged the NPIs with the National Plan and Provider Enumeration System (NPPES) to obtain

HBO facility contact information. It is important to note that this sampling approach does not guarantee that all potentially affected stakeholders in the model states were identified and included in the sample.

Survey invitations went to the full sample of eligible facilities. We mailed invitation letters containing instructions for completing the survey during the week of July 17, 2017. We mailed one reminder postcard to non-responding sample members the week of July 31, 2017. We were able to identify email addresses for 44 facilities in the sample and sent out an email reminder to these facilities during the weeks of July 31, 2017 and August 21, 2017.[10] There was no incentive provided for completing this survey.

Table E.4. Online survey response rates

	Total sample	Ineligible or Duplicate*	Nonresponse	Completes	Response rate**
Illinois	52	4	35	13	27.1%
Michigan	49	3	35	11	23.9%
New Jersey	49	7	34	8	19.0%
Total	**150**	**14**	**104**	**32**	**23.5%**

*Facilities were ineligible if they did not serve Medicare beneficiaries (N=1). Duplicates were removed from the sample based on overlapping facility name and address (N=13).

**Response rate is calculated as: (number of completes) / (total sample – ineligible or duplicate).

Online survey analysis. Survey data were analyzed by running cross-tabulations and summary statistics within the computer-assisted interviewing (CAI) system as well as through MS Excel analysis templates. We ran the analysis by question, calculating summary statistics for our groups of interest. Because the survey was administered to samples of facilities constructed by matching claims data with CPI reports of prior authorization submissions, it is not based on a probability or census sample of all affected facilities in the model states.

CPI Interviews

In October 2017, following other data collection activities and analyses, 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 potential model expansion. Prevailing themes from the interview are summarized in the evaluation report.

[10] Timing of the e-mail reminder depended on when the e-mail address was identified. For facilities where the e-mail address was identified during the first round of the contact information locating process, the e-mail reminder was sent the week of July 31, 2017. For facilities where the e-mail address was identified in the second and final round of the contact information locating process, the reminder e-mail was sent the week of August 21, 2017.

153 East 13th Street, Suite 1400
Erie, PA 16503
814-480-8732
814-456-5524 FAX
www.provider-resources.com

Beneficiary Interview Questionnaire

Interview Start Time	
Person's Name	

Introduction

Hi, Mr. / Mrs. / Ms. _____.

Start here IF WE ARE RECRUITING PATIENT:

My name is _____, and I'm visiting your facility to talk about your experience with getting your hyperbaric oxygen (HBO) treatment. Would it be okay if we spoke for about 15 minutes?

If No ➔ Give card with contact information and say: "If anything comes to mind and you want to chat later, just give us a call or send us an email and we will contact you and schedule a time to follow up."

If Yes ➔ Great. Thank you. I'm helping Medicare learn more about how the prior authorization payment model for HBO treatment is affecting people. Do you have Medicare?

> If No ➔ Ok, we are only interviewing Medicare patients at this time. Thank you for your time. Take care and have a nice day. **End**.
>
> If Yes ➔ Great. I would like to hear more about your experience.

INTRODUCTION:

Before we get started, would it be ok if I record this call so I can refresh my memory later? The recording will be kept confidential and will be destroyed once we complete our evaluation.

If No ➔ Ok, no problem. I'll take notes.

If Yes ➔ Thank you.

Let's get started.

Start here IF PATIENT IS PRE-SCHEDULED:

My name is _____, and I'm visiting your facility to talk about your experience with getting your hyperbaric oxygen (HBO) treatment. [STAFF MEMBER NAME] mentioned that you would like to talk with us about your experience.

INTRODUCTION:

Before we get started, would it be ok if I record this call so I can refresh my memory later? The recording will be kept confidential and will be destroyed once we complete our evaluation.

If No ➔ Ok, no problem. I'll take notes.

If Yes ➔ Thank you.

Let's get started.

Healthcare Utilization

1. Are you currently receiving care at [facility name] or are you a caregiver of someone receiving care? [NOTE: Replace "you" below with patient's name/title if person is a caregiver]

2. Are you currently receiving HBO treatment?

3. Can I ask for what condition your doctor recommended getting HBO treatment?

If person is currently receiving treatment (Questions 4-6):

4. How long have you been getting HBO treatments?

5. How often do you receive treatment?
   - ☐ 5 times per week
   - ☐ Less than 5 times per week
   - ☐ Other: _____

6. How long are your treatment sessions?
   - ☐ One hour per session
   - ☐ Two hours per session
   - ☐ Three or more hours per session

Medical Necessity

7. What is your understanding of what HBO therapy is supposed to do for your condition? Do you feel it is working or believe it will work?

8. Can you tell me about any other treatments you've tried besides HBO therapy for the same condition?

9. Have you received HBO therapy for other conditions before? If yes, please share your experience.

Access to Treatment

10. Do you know what prior authorization means??
    - Do you understand how it works?

11. Can you tell me about getting your HBO therapy set up after your doctor ordered it? (Probe and listen for the following):
    - What was the referral process like? Who called the facility, and when?
    - What intake information did the facility ask for (e.g. fax from doctor, via phone, hardcopy orders, etc.); and when?
    - How long did you wait/ have you been waiting to receive HBO treatment?
    - How many times was a request submitted? How many times was a request non-approved?

If patient is receiving treatment (Questions 12-16):

12. [If not included in previous response] When did HBO therapy first begin, and what had to happen before it could be scheduled (e.g. an opening, PA, paperwork, payment)?

13. Can you tell me about getting prior authorization from Medicare to pay for your HBO therapy? (Listen for the following):
    - Who submitted a PAR, and when?
    - What was their awareness of the medical necessity requirement and their eligibility status?
    - Was it approved, when, and why or why not?

14. [If not included in previous response] Do you know if Medicare is paying for any part of your HBO therapy?
    - If yes, please explain.
    - If no, do you have a hard time paying for HBO if you cover the payment yourself? Do you have a hard time getting insurance to cover it?

15. Have you ever missed a treatment or part of a treatment for any reason?
    If yes: “Please explain why you missed treatment” and ask the next question;
    If no, skip the next question. Listen for direct and indirect causes, including:
    - Cost of obtaining PA
    - Transportation to or from HBO therapy
    - Disagreement with doctor about needing it
    - HBO facility availability/ scheduling

16. What was the result of missing HBO therapy? (Listen and probe for):
    - Physical symptoms (pain, bleeding, etc.)
    - Other healthcare utilization (doctor visit, urgent care, ER, etc.)
    - Self-care, including costs (wound care supplies, over the counter treatments)
    - Physician's stated prognosis (slower healing, needing more sessions)
    - Change in treatment plan (medications, inpatient rehab, etc.)

Quality of Care

17. Do you have any anxiety or stress associated with HBO treatment?
    - Probe: Waiting for HBO treatment? Receiving HBO treatment? The HBOT machine itself? If yes, how does it make you feel, and why?

18. Do you have any stress associated with financial payment for your HBO treatment?
    - Probe: Would you be able to pay for it without Medicare? If yes, how does it make you feel, and why?

19. Is there anything you would like to share with me about your HBO treatment or Medicare's prior authorization program for HBO Therapy?

Thank you very much for your time.

[If approved by facility: We would like to send you a thank you note for taking the time to speak with us. Could you please provide us with your mailing address?]

If Yes ➔ Great. Thank you.
If No ➔ Ok thank you and have a nice day.

153 East 13th Street, Suite 1400
Erie, PA 16503
814-480-8732
814-456-5524 FAX
www.provider-resources.com

HBO Facility Site Visit Guide
Interviewer Discussion with Staff

Introduction:

Hello, my name is [Your Name] and I am here today because we would like to meet with you for about 20 minutes to discuss the Prior Authorization process for non-emergent Hyperbaric Oxygen treatment. The Centers for Medicare & Medicaid Services (CMS) has contracted with Mathematica Policy Research (MPR) and Provider Resources, Inc. (PRI), to conduct an independent evaluation of the Prior Authorization Model. The evaluation will examine how the prior authorization program is working, effects it is having on various stakeholder groups, and areas for improvement moving forward.

The information provided by all participants will be kept strictly confidential.

IF RECRUITING STAFF/CLINICIANS:

We have been meeting with [Facility Contact] at your facility and he/she said you would be available to speak with us today. Is now a good time?

If Yes ➔ Great.

If No ➔ I understand how busy you are. We will be here all day. Is there another time today that works better for you?

If Yes ➔ Great. We will come back at the new time.

If No ➔ I understand and appreciate how busy you are. We can handle it a number of ways:
a) We can email you the questions and ask you to email your responses back to us at RSNAT-HBO@provider-resources.com.
b) We can reschedule and conduct the interview over the phone.

ALL INTERVIEWS:

If possible, we would like to record our interview. Is that okay with you?
a) If yes - Great.
b) If no - Okay, I will take notes.

Ready? Let's begin.

Staff Interview Questionnaire

Staff Person's Name	
Email Address	
Phone Number	

a. Before we begin, would you mind confirming your full name and providing your email address and phone number in case we have any follow-up questions?

The first eight questions inquire about your experience with HBO and the prior authorization request process at your facility:

1. Please describe your current role and experience with HBO treatment.
   Probes:
   a) Clinician, Management/Executive, Administrative Support, Other
   b) Number of years in similar and other related roles
   c) Number of years specifically involved with HBO treatment or conditions that result in the need for HBO therapy

2. Please describe the population(s) you serve in your current role.
   Probes:
   a) Total number of patients receiving treatment monthly, annually
   b) Medicare Only, Dual Eligible, Medicaid Only, Private Pay, Commercial
   c) Medicare FFS vs Medicare Advantage
   d) Geographical service area

3. How did you learn about the Prior Authorization Model for non-emergent HBO treatment?
   Probes:
   a) Medical necessity rules and guidelines
   b) Prior Authorization request documentation requirements
   c) Prior Authorization request process, including responsibilities and timelines
   d) Prior Authorization request determinations (affirmed/non-affirmed)

4. Since implementation of the Prior Authorization Model for non-emergent HBO treatment, have you needed to obtain any clarification about the model? If yes, from whom was the clarification sought/received and why?

5. Please describe the Prior Authorization Request (PAR) process that is generally followed at your facility.
   Probe:
   a) If you are not involved in the PAR process, please describe what you know about it to the best of your ability.
   b) Please describe your facility's process for obtaining Medical Necessity information for completing a Prior Authorization Request.

6. Please describe what happens if your facility's request for Prior Authorization is non-affirmed.
   Probes:
   a) Interaction with MAC reviewer
   b) Communication with referring physician
   c) Communication with beneficiary
   d) Other follow up - please explain

7. Does your facility begin non-emergent HBO treatment for a patient before receiving an affirmative Prior Authorization Request decision? If, no, please provide examples of those instances.

8. What is the role of the HBO treatment center/management company in providing education on a proactive basis to the referring clinical community in regard to PA requirements for HBO treatment?

The next two questions are for the site director, or someone familiar with site operations:

9. Who supervises the HBO session? [If not a physician, probe to determine if the physician is nearby]. What do they do as part of the supervision?

10. Do physicians/other professionals bill independently or are their services included in the facility charge?

The next five questions inquire about your opinion of the non-emergent HBO PA model and how you think it has affected delivery of HBO services:

11. In your opinion, how is the PA Model affecting the provision of non-emergent HBO treatment, including:
    a) Timeliness of care for your patients?
    b) Quality of care for your patients?
    c) Health outcomes of your patients?
    d) Number of people receiving HBO treatment
    e) Staffing of HBO facilities

12. What do you think about the administration of Medicare's PA Model for non-emergent HBO treatment?
    Probes:
    a) Clarity and consistency of PA request requirements
    b) Appropriateness of MAC requested documentation
    c) Clarity and consistency of PA determinations rendered by MAC
    d) Communication with Medicare MAC reviewers

e) Coordination with prescribing physician or other stakeholders required to provide documentation

13. Do you have any recommendations for improving any aspect of the PA Model for non-emergent HBO treatment?
    Probes:
    a) Documentation
    b) Communication with MAC
    c) MAC reviewer interpretations
    d) Timeframes
    e) Other stakeholders (e.g. physicians, patients)
    f) Other

14. Is there any other information you would like us to know about the CMS PA Model for non-emergent HBO treatment?

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

APPENDIX F

YEAR 1 SURVEY TOPLINE RESULTS

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

Medicare Prior Authorization Model for Non-Emergent Hyperbaric Oxygen Therapy Evaluation

Centers for Medicare & Medicaid Services

Appendix F
Year 1 Stakeholder Survey
Final Topline Results
October, 5, 2017

Total n = 33 HBO facility stakeholders in Illinois, Michigan, and New Jersey

Field period: July 18, 2017, to September 18, 2017

Tables show percentages of respondents selecting each response category. All percentages are rounded to the nearest whole number. Tables may not always add to 100 percent due to rounding. For multiple response questions, table totals may exceed 100 percent.

Results are based on a census of hyperbaric oxygen treatment providers in three HBO prior authorization model states. Results are not generalizable to the stakeholder population as a whole in those states nor to any particular subgroup. Inferential statistical analysis, including margins of error and tests of significance, are not appropriate for this type of sample. No weighting has been applied. The results presented below are descriptive in nature.

Some questions are not asked of all respondents. The base for each question is noted above each table.

A1. Are you employed by, do you provide services at a hyperbaric oxygen treatment or wound care center? [Select one only]

	HBO Treatment Facilities n = 33
Yes	33
No	0

A2. Does your facility currently provide services to Medicare Part B or dual eligible beneficiaries? [Select one only]

	HBO Treatment Facilities n = 33
Yes	32
No	1

A3. In which state is your facility located? [Select one only]

Based on respondents from hyperbaric oxygen facilities or wound care centers who currently provide services to Medicare Part B or dual eligible beneficiaries, n = 32

	HBO Treatment Facilities n = 32
Illinois	13
Michigan	11
New Jersey	8
None of these states	0

A4. Which of the following best describes your role at this facility? [Select one only]

Based on respondents from hyperbaric oxygen facilities or wound care centers who currently provide services to Medicare Part B or dual eligible beneficiaries, n = 32

	HBO Treatment Facilities n = 32
Medical director	1
Supervising physician	0
Program director or program manager	16
HBO technician or safety director	6
Clinical coordinator or nurse manager	6
Other (specify)	3

A5. In March 2015, CMS implemented the non-emergent Hyperbaric Oxygen (HBO) prior authorization payment model in Michigan, followed by expansion to Illinois and New Jersey in July 2015. This model requires HBO treatment facilities to submit prior authorization requests for non-emergent HBO therapy for some conditions. How familiar are you with the Medicare payment model for HBO prior authorization? [Select one only]

Based on respondents from hyperbaric oxygen facilities or wound care centers who currently provide services to Medicare Part B or dual eligible beneficiaries, n = 32

	HBO Treatment Facilities n = 32
Very familiar	26
Somewhat familiar	6
Not too familiar	0
Not at all familiar	0

A5a. Is there someone else at your facility who is more familiar with the Prior Authorization Model for HBO therapy? [Select one only]

Question was logically skipped for all respondents, as they answered either very familiar or somewhat familiar in QA5.

	HBO Treatment Facilities n = 32
Yes	0
No	0

A6. How did you first learn about the prior authorization payment model for HBO treatment? [Select all that apply]

Based on respondents who are familiar with the prior authorization model, n = 32

	HBO Treatment Facilities n = 32
Employer-sponsored trainings, meetings, and/or materials	13
Centers for Medicare and Medicaid Services (CMS)-sponsored trainings, meetings, and/or materials	8
Information or training offered by HBO management networks or professional associations	6
Other facility staff	7
Independent learning	6
Other (specify)	1

B1. Approximately how many *initial* prior authorization requests (PARs) for non-emergent HBO therapy has your facility submitted in the past 12 months? Initial PARs are the first request submitted for a course of HBO therapy for a particular patient; please do not include resubmissions in your answer.

Based on respondents who are familiar with the prior authorization model, n = 32

	HBO Treatment Facilities n = 32
None	1
1–9	10
10–19	13
20–29	2
30 or more	6

B2. Below please give your best estimate on what percentage of your facility's *initial* prior authorization requests has resulted in each outcome. Your percentage should sum to 100%.

Based on respondents from hyperbaric oxygen facilities that have submitted a prior authorization request in the past 12 months, n = 32

	HBO Treatment Facilities n = 32	
	Median % reported	Mean % reported
Affirmed upon initial submission	63.5	57.6
Affirmed after one or more resubmissions	11	20.1
Not affirmed	10	20.3
In process/No outcome to date	0	4.4

B3. About how long is the typical response time from your Medicare Administrative Contractor (MAC) for an *initial* request for HBO prior authorization? [Select one only]

Based on respondents from hyperbaric oxygen facilities that have submitted a prior authorization request in the past 12 months, n = 32

	HBO Treatment Facilities n = 32
1–5 business days	4
6–10 business days	19
11–15 business days	2
More than 15 business days	6
Blank Response	1

B4. Since the 2015 implementation of the prior authorization payment model, has your facility ever provided non-emergent HBO treatment for a Medicare beneficiary *while waiting for a prior authorization request to be affirmed?* [Select one only]

Based on respondents from hyperbaric oxygen facilities that have submitted a prior authorization request in the past 12 months, n = 32

	HBO Treatment Facilities n = 32
Yes	9
No	22
Blank Response	1

B4a. Does your facility currently provide HBO treatment to any Medicare beneficiaries *before their prior authorization request is affirmed,* or does your facility no long do this?

Based on respondents from hyperbaric oxygen facilities that provide non-emergent HBO treatment while waiting for a prior authorization request to be affirmed, n = 9

	HBO Treatment Facilities n = 9
Yes, we currently provide treatment to some beneficiaries before their HBO PAR is affirmed	3
No, no longer do this	6

B5. The following six conditions require prior authorization for non-emergent HBO therapy:

1. Preparation and preservation of compromised skin grafts (not for primary management of wounds)
2. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management
3. Osteoradionecrosis as an adjunct to conventional treatment
4. Soft Tissue radionecrosis as an adjunct to conventional treatment
5. Actinomycrosis only as an adjunct conventional therapy when the disease process is refractory to antibiotics and surgical treatment
6. Diabetic wounds of the lower extremities in patients who meet the following three criteria:
   a. Patients has Type I or Type II Diabetes and who has a lower extremity wound that is due to diabetes
   b. Patient has wound classified as Wagner grade III or higher
   c. Patient has failed an adequate course of wound therapy as defined in the NCD

How familiar are you with the prior authorization *medical necessity requirements* for each of these conditions?

Based on respondents from hyperbaric oxygen facilities that have submitted a prior authorization request in the past 12 months, n = 32

	Very Familiar	Somewhat Familiar	Not Too Familiar	Not At All Familiar	Blank Response	Total N=32
a. Compromised skin grafts	23	7	1	0	1	32
b. Chronic refractory osteomyelitis	25	5	1	0	1	32
c. Osteoradionecrosis	26	4	1	0	1	32
d. Soft Tissue radionecrosis	26	5	0	0	1	32
e. Actinomycrosis	8	4	12	7	1	32
f. Diabetic wounds of the lower extremities	28	3	0	0	1	32

B6. For each condition below, would you say current prior authorization requirements are an accurate or inaccurate indication of medical necessity for HBO therapy for particular beneficiaries?

Based on respondents from hyperbaric oxygen facilities that have submitted a prior authorization request in the past 12 months, n = 32

	Very Accurate	Mostly Accurate	Mostly Inaccurate	Very Inaccurate	Don't Know	Blank Response	Total N=32
a. Compromised skin grafts	6	15	4	2	4	1	32
b. Chronic refractory osteomyelitis	6	19	4	1	1	1	32
c. Osteoradionecrosis	9	14	3	2	3	1	32
d. Soft Tissue radionecrosis	6	17	6	1	1	1	32
e. Actinomycrosis	4	5	0	0	15	8	32
f. Diabetic wounds of the lower extremities	7	15	7	1	1	1	32

B7. In your experience, how easy or difficult is it to have a prior authorization request affirmed for each of the conditions below?

Based on respondents from hyperbaric oxygen facilities that have submitted a prior authorization request in the past 12 months, n = 32

	Very Easy	Easy	Difficult	Very Difficult	No experience submitting HBO PARs for this condition	Blank Response	Total N=32
a. Compromised skin grafts	1	10	4	5	11	1	32
b. Chronic refractory osteomyelitis	0	10	17	4	0	1	32
c. Osteoradionecrosis	0	10	14	5	2	1	32
d. Soft Tissue radionecrosis	1	10	12	6	2	1	32
e. Actinomycrosis	0	2	3	1	25	1	32
f. Diabetic wounds of the lower extremities	1	10	11	9	0	1	32

B8. How often, if ever, do you need to gather supporting information or documentation from *other provider or facilities* to include with a prior authorization request for one of your patients?

Based on respondents from hyperbaric oxygen facilities that have submitted a prior authorization request in the past 12 months, n = 32

	HBO Treatment Facilities n = 32
Very often	26
Often	4
Sometimes	1
Hardly ever	0
Never	0
Blank Response	1

B8a. In general, how easy or difficult is it to get supporting information for prior authorization requests from *other providers or facilities*?

Based on respondents from hyperbaric oxygen facilities that have to gather supporting information and documentation from other providers or facilities to include in a PAR for a patient, n = 32

	HBO Treatment Facilities n = 32
Very easy	1
Easy	11
Difficult	13
Very difficult	6
Blank Response	1

B8b. Which of the following challenges, if any, have you experienced when gathering medical necessity *documentation from other providers or facilities*? [Select all that apply]

Based on respondents from hyperbaric oxygen facilities that have to gather supporting information and documentation from other providers or facilities to include in a PAR for a patient, n = 32

	HBO Treatment Facilities n = 32
Slow response time	26
Inaccurate documentation	16
Missing documentation	23
Other (specify)	5
Blank Response	1

B8c. When gathering medical necessity documentation for HBO PARs, how far back in a patient's medical history do you typically need to go?

Based on respondents from hyperbaric oxygen facilities that have submitted a prior authorization request in the past 12 months, n = 32

	HBO Treatment Facilities n = 32
Prior 12 months	23
13-24 months	6
25-60 months	0
More than 60 months	2
Blank Response	1

B9. Have HBO prior authorization requests submitted by your facility been non-affirmed for any of the following reason? [Select all that apply]

Based on respondents from hyperbaric oxygen facilities that have submitted a prior authorization request in the past 12 months, n = 32

	HBO Treatment Facilities n = 32
Inaccurate clinical documentation	4
Incomplete clinical documentation	14
Missing technical information such as names, dates or signatures	10
Does not meet medical necessity criteria for condition	25
Blank Response	1

B10. When PARs for HBO therapy are non-affirmed, is it typically easy or difficult to determine what needs to be changed or addressed for a resubmission to be affirmed? [Select one only]

Based on respondents from hyperbaric oxygen facilities that have submitted a prior authorization request in the past 12 months, n = 32

	HBO Treatment Facilities n = 32
Very easy	2
Easy	13
Difficult	8
Very Difficult	7
Blank Response	2

B11. How often do you contact your Medicare Administrative Contractor (MAC) for clarification on or assistance with a particular HBO PAR? [Select one only]

Based on respondents from hyperbaric oxygen facilities that have submitted a prior authorization request in the past 12 months, n = 32

	HBO Treatment Facilities n = 32
Very often	1
Often	6
Sometimes	12
Hardly ever	5
Never	7
Blank Response	1

B11a. In general, how helpful is your MAC when you contact them for clarification on or assistance with a particular HBO PAR? [Select one only]

Based on respondents from hyperbaric oxygen facilities that have contacted MAC for clarification or assistance, n = 25

	HBO Treatment Facilities n = 25
Very helpful	4
Somewhat helpful	13
Not too helpful	5
Not helpful at all	2
Blank Response	1

B12. Peer-to-peer reviews occur when an HBO facility physician and a MAC physician discuss the reasoning behind a particular PAR outcome. Have physicians at your facility participated in any peer-to-peer discussions with MAC physicians about HBO prior authorization request determinations? [Select one only]

Based on respondents from hyperbaric oxygen facilities that have submitted a prior authorization request in the past 12 months, n = 32

	HBO Treatment Facilities n = 32
Yes	14
No	14
Don't Know	3
Blank Response	1

B12a. Based on your facility's experience, how helpful have peer-to-peer discussions been in resolving questions about PAR outcomes? [Select one only]

Based on respondents from hyperbaric oxygen facility physicians that have participated in a peer-to-peer discussion with a MAC physician, n =14

	HBO Treatment Facilities n = 14
Very helpful	3
Somewhat helpful	3
Not too helpful	2
Not helpful at all	6
Don't know	0
Blank Response	0

C1. How has your facility's overall case load changed, if at all, since prior authorization for HBO therapy was implemented in 2015? [Select one only]

Based on respondents from hyperbaric oxygen facilities that have submitted a prior authorization request in the past 12 months, n = 32

	HBO Treatment Facilities n = 32
Increased a lot	3
Increased some	3
Decreased some	7
Decreased a lot	12
No effect at all	6
Blank Response	1

C2. How much, if at all, has the HBO prior authorization model increased time spent on administrative duties by staff at your facility? [Select one only]

Based on respondents from hyperbaric oxygen facilities that have submitted a prior authorization request in the past 12 months, n = 32

	HBO Treatment Facilities n = 32
A lot	26
Some	4
Only a little	1
None at all	0
Blank response	1

C3. Since model implementation in 2015, have any of your patients delayed or canceled scheduled HBO treatments because they were not affirmed for HBO therapy under prior authorization? [Select one only]
Based on respondents from hyperbaric oxygen facilities that have submitted a prior authorization request in the past 12 months, n = 32

	HBO Treatment Facilities n = 32
Yes	28
No	3
Blank Response	1

C3a. 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]

Based on respondents from hyperbaric oxygen facilities that have had patients delay or cancel HBO therapy because they were non-affirmed, n = 28

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

C4. In your experience, has the prior authorization requirement for non-emergent HBO therapy resulted in some beneficiaries who are not affirmed for HBO relying on *emergency care* to treat their condition? [Select one only]

Based on respondents from hyperbaric oxygen facilities that have submitted a prior authorization request in the past 12 months, n = 32

	HBO Treatment Facilities n = 32
Yes	18
No	13
Blank Response	1

C5. In your experience, are some beneficiaries experiencing adverse health outcomes as a result of not being affirmed for HBO therapy under the prior authorization model? [Select one only]

Based on respondents from hyperbaric oxygen facilities that have submitted a prior authorization request in the past 12 months, n = 32

	HBO Treatment Facilities n = 32
Yes	26
No	5
Blank Response	1

D1. First, is your HBO treatment or wound care facility affiliated with a hospital?

Based on respondents from hyperbaric oxygen facilities that have submitted a prior authorization request in the past 12 months, n = 32

	HBO Treatment Facilities n = 33
Yes	32
No	0

D2. Is your work facility independently owned and operated, or managed as a part of a larger HBO network?

Based on respondents from hyperbaric oxygen facilities that have submitted a prior authorization request in the past 12 months, n = 32

	HBO Treatment Facilities n = 32
Independently owned and operated	4
Managed as part of a larger network	21
Other (specify)	7

APPENDIX G

STATISTICAL POWER TO DETECT MODEL EFFECTS ON HBO UTILIZATION AND ADVERSE OUTCOMES

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

In this appendix, we provide an analysis of the available statistical power to detect effects of the HBO prior authorization program on different outcomes related to HBO utilization. Statistical power analysis uses the variance of the impact estimates to demonstrate the precision with which the impacts are measured. We present precision estimates for utilization outcomes among beneficiaries, including any HBO utilization, HBO utilization with appropriate standard therapy, and several adverse outcomes (emergency department visits, unplanned hospital admissions, and death).

The primary factor that determines statistical power is the sample size used to generate estimates. All other things equal, larger sample sizes result in more precise estimates and therefore increase statistical power. Other factors that affect statistical power include the observed variance of the outcomes, design effects due to weighting, and design effects due to clustering. Each of these factors has an inverse relationship with statistical power: as they increase, statistical power decreases. The design effect due to weighting is a measure of the increase in the variance of the estimate due to unequal weighting. For analyses using beneficiaries, we used this weighting to match model states with comparison states and balance several measures on beneficiaries in the comparison states with those in model states.

Using a difference-in-differences (DD) analytic approach, statistical power is also affected by the extent to which the baseline observations predict the post-intervention outcomes, as determined by two factors: (1) the overlap in pre- and post-intervention samples and (2) the correlation between the covariates used in the model and the outcome measure. As this correlation increases, the variance in the predicted outcome decreases, thereby increasing statistical power. This effect is amplified the more the pre- and post-intervention samples overlap. Analyses with strong predictor variables and high proportions of overlap in the samples will have greater statistical power than those with less of either or both factors.

Table G.1 presents 95 percent and 80 percent half-confidence intervals for the various beneficiary-level utilization outcomes. These intervals are based on the observed variance of the DD impact estimates, which encapsulates all of the factors described above. The 95 percent confidence interval estimates account for a type I error rate of 5 percent; in other words, if the data were resampled 100 times, 95 of the estimated confidence intervals would cover the true difference in means. Similarly, the 80 percent confidence interval estimates account for a type I error rate of 20 percent; 80 of the 100 re-estimated confidence intervals would cover the true difference in means. The confidence interval for outcome J (CI_J) is calculated using the following formula:

$$CI_J = \hat{\beta}_J \pm (Z_{1-\alpha/2} * S_J)$$

where $\hat{\beta}_J$ is the impact estimate for outcome J, $Z_{1-\alpha/2}$ is the critical value of the normal distribution, with $\alpha = 0.05$ for the 95 percent confidence intervals and $\alpha = 0.20$ for the 80 percent confidence intervals, and S_J is the standard error for the impact estimate. Separate results are provided for beneficiaries with any condition and those with diabetic lower extremity wounds.

Table G.1. Statistical precision for quarterly HBO utilization outcomes among beneficiaries with diabetic lower extremity wounds

Outcome and sample	Beneficiary quarterly observations in model states	Beneficiary quarterly observations in comparison states	95% half-confidence interval	80% half-confidence interval	Observed effect
Probability of HBO utilization	**605,314**	**592,045**	**0.0980**	**0.0641**	**-0.30*** **
Beneficiaries in Illinois	231,155	138,833	0.1176	0.0769	-0.19**
Beneficiaries in Michigan	183,603	136,897	0.1372	0.0897	-0.15*
Beneficiaries in New Jersey	190,556	316,315	0.0980	0.0641	-0.51***
Number of HBO treatments	**605,314**	**592,045**	**0.0196**	**0.0128**	**-0.06*** **
Beneficiaries in Illinois	231,155	138,833	0.0392	0.0256	-0.02
Beneficiaries in Michigan	183,603	136,897	0.0392	0.0256	-0.03†
Beneficiaries in New Jersey	190,556	316,315	0.0196	0.0128	-0.11***
Probability of HBO utilization with appropriate history of standard therapy	**605,314**	**592,045**	**0.0392**	**0.0256**	**-0.02†**
Beneficiaries in Illinois	231,155	138,833	0.0392	0.0256	-0.00
Beneficiaries in Michigan	183,603	136,897	0.0392	0.0256	-0.02
Beneficiaries in New Jersey	190,556	316,315	0.0392	0.0256	-0.05**
Number of HBO treatments with appropriate history of standard therapy	**605,314**	**592,045**	**0.0196**	**0.0128**	**-0.02***
Beneficiaries in Illinois	231,155	138,833	0.0196	0.0128	-0.01†
Beneficiaries in Michigan	183,603	136,897	0.0196	0.0128	-0.01
Beneficiaries in New Jersey	190,556	316,315	0.0196	0.0128	-0.03**

Note: The model states included: Illinois, Michigan, or New Jersey. The comparison states included: Delaware, District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, Virginia [selected areas], or Wisconsin.

[a] Test of a difference different from 0 has less than 80 percent power (1 minus type II error).

† $p < .20$, * $p < .05$, ** $p < .01$, *** $p < .001$.

Table G.2. Statistical precision for quarterly HBO utilization outcomes among beneficiaries with any included condition

Outcome and sample	Beneficiary quarterly observations in model states	Beneficiary quarterly observations in comparison states	95% half-confidence interval	80% half-confidence interval	Observed effect
Probability of HBO utilization	**741,511**	**715,824**	**0.0980**	**0.0641**	**-0.34*****
Beneficiaries in Illinois	280,319	168,919	0.1176	0.0769	-0.18**
Beneficiaries in Michigan	223,147	157,573	0.1176	0.0769	-0.24***
Beneficiaries in New Jersey	238,045	389,332	0.0980	0.0641	-0.57***
Number of HBO treatments	**741,511**	**715,824**	**0.0392**	**0.0256**	**-0.08*****
Beneficiaries in Illinois	280,319	168,919	0.0392	0.0256	-0.03†
Beneficiaries in Michigan	223,147	157,573	0.0392	0.0256	-0.06**
Beneficiaries in New Jersey	238,045	389,332	0.0392	0.0256	-0.14***

Note: The model states included: Illinois, Michigan, or New Jersey. The comparison states included: Delaware, District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, Virginia [selected areas], or Wisconsin.

[a] Test of a difference different from 0 has less than 80 percent power (1 minus type II error).

† $p < .20$, * $p < .05$, ** $p < .01$, *** $p < .001$.

Table G.3. Statistical precision for quality of care and adverse outcomes among beneficiaries with diabetic lower extremity wounds

Outcome and sample	Beneficiary quarterly observations in model states	Beneficiary quarterly observations in comparison states	95% half-confidence interval	80% half-confidence interval	Observed effect
Probability of HBO utilization with physician supervision	**605,314**	**592,045**	**0.0980**	**0.0641**	**-0.32*** **
Beneficiaries in Illinois	231,155	138,833	0.1372	0.0897	-0.22***
Beneficiaries in Michigan	183,603	136,897	0.1372	0.0897	-0.16*
Beneficiaries in New Jersey	190,556	316,315	0.1176	0.0769	-0.54***
Proportion of HBO treatments with physician supervision	**6,175**	**5,260**	**0.0588**	**0.0384**	**-0.04†**
Beneficiaries in Illinois	2,048	939	0.0588	0.0384	-0.03
Beneficiaries in Michigan	1,950	1,245	0.0588	0.0384	-0.01
Beneficiaries in New Jersey	2,177	3,076	0.0784	0.0513	-0.15***
Probability of ED visit	605,314	592,045	0.5096	0.3332	-0.78**
Beneficiaries in Illinois	231,155	138,833	0.6468	0.4229	-0.30
Beneficiaries in Michigan	183,603	136,897	0.7056	0.4614	-1.03**
Beneficiaries in New Jersey	190,556	316,315	0.6860	0.4485	-1.10**
Number of ED visits	**605,314**	**592,045**	**0.0196**	**0.0128**	**-0.01†**
Beneficiaries in Illinois	231,155	138,833	0.0196	0.0128	-0.00
Beneficiaries in Michigan	183,603	136,897	0.0196	0.0128	-0.02*
Beneficiaries in New Jersey	190,556	316,315	0.0196	0.0128	-0.01†
Probability of unplanned hospitalization	**605,314**	**592,045**	**0.4704**	**0.3076**	**-0.57***
Beneficiaries in Illinois	231,155	138,833	0.5880	0.3845	-0.26
Beneficiaries in Michigan	183,603	136,897	0.6468	0.4229	-0.66*
Beneficiaries in New Jersey	190,556	316,315	0.6272	0.4101	-0.85**
Number of unplanned hospitalizations	**605,314**	**592,045**	**0.0000**	**0.0000**	**0.00**
Beneficiaries in Illinois	231,155	138,833	0.0196	0.0128	-0.00
Beneficiaries in Michigan	183,603	136,897	0.0196	0.0128	-0.00
Beneficiaries in New Jersey	190,556	316,315	0.0196	0.0128	-0.01†
Probability of death	**605,314**	**592,045**	**0.1960**	**0.1282**	**-0.24***
Beneficiaries in Illinois	231,155	138,833	0.2352	0.1538	-0.13
Beneficiaries in Michigan	183,603	136,897	0.2548	0.1666	-0.29*
Beneficiaries in New Jersey	190,556	316,315	0.2548	0.1666	-0.30*

Note: The model states included: Illinois, Michigan, or New Jersey. The comparison states included: Delaware, District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, Virginia [selected areas], or Wisconsin.

[a] Test of a difference different from 0 has less than 80 percent power (1 minus type II error).

† $p < .20$, * $p < .05$, ** $p < .01$, *** $p < .001$.

Table G.4. Statistical precision for adverse outcomes related to diabetic lower extremity wounds

Outcome and sample	Beneficiary quarterly observations in model states	Beneficiary quarterly observations in comparison states	95% half-confidence interval	80% half-confidence interval	Observed effect
Probability of ED visit for lower extremity wound	**605,314**	**592,045**	**0.0392**	**0.0256**	**0.05****
Beneficiaries in Illinois	231,155	138,833	0.0392	0.0256	0.06*
Beneficiaries in Michigan	183,603	136,897	0.0588	0.0384	0.05*
Beneficiaries in New Jersey	190,556	316,315	0.0588	0.0384	0.05†
Number of ED visits for lower extremity wound	**605,314**	**592,045**	**0.0000**	**0.0000**	**0.00***
Beneficiaries in Illinois	231,155	138,833	0.0000	0.0000	0.00†
Beneficiaries in Michigan	183,603	136,897	0.0000	0.0000	0.00†
Beneficiaries in New Jersey	190,556	316,315	0.0000	0.0000	0.00†
Probability of unplanned hospitalization for lower extremity wound	**605,314**	**592,045**	**0.0392**	**0.0256**	**-0.01**
Beneficiaries in Illinois	231,155	138,833	0.0588	0.0384	0.01
Beneficiaries in Michigan	183,603	136,897	0.0588	0.0384	-0.02
Beneficiaries in New Jersey	190,556	316,315	0.0588	0.0384	-0.02
Number of unplanned hospitalizations for lower extremity wound	**605,314**	**592,045**	**0.0000**	**0.0000**	**0.00**
Beneficiaries in Illinois	231,155	138,833	0.0000	0.0000	0.00
Beneficiaries in Michigan	183,603	136,897	0.0000	0.0000	-0.00
Beneficiaries in New Jersey	190,556	316,315	0.0000	0.0000	-0.00
Probability of amputation	**605,314**	**592,045**	**0.1176**	**0.0769**	**-0.06**
Beneficiaries in Illinois	231,155	138,833	0.1568	0.1025	-0.11†
Beneficiaries in Michigan	183,603	136,897	0.1764	0.1153	0.09
Beneficiaries in New Jersey	190,556	316,315	0.1764	0.1153	-0.14†

Note: The model states included: Illinois, Michigan, or New Jersey. The comparison states included: Delaware, District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, Virginia [selected areas], or Wisconsin.

[a] Test of a difference different from 0 has less than 80 percent power (1 minus type II error).

† $p < .20$, * $p < .05$, ** $p < .01$, *** $p < .001$.

Table G.5. Statistical precision for quality of care and adverse outcomes among beneficiaries with any included condition

Outcome and sample	Beneficiary quarterly observations in model states	Beneficiary quarterly observations in comparison states	95% half-confidence interval	80% half-confidence interval	Observed effect
Probability of HBO utilization with physician supervision	**741,511**	**715,824**	**0.0980**	**0.0641**	**-0.36*****
Beneficiaries in Illinois	280,319	168,919	0.1176	0.0769	-0.20**
Beneficiaries in Michigan	223,147	157,573	0.1176	0.0769	-0.24***
Beneficiaries in New Jersey	238,045	389,332	0.0980	0.0641	-0.60***
Proportion of HBO treatments with physician supervision	**7,981**	**6,902**	**0.0392**	**0.0256**	**-0.03**
Beneficiaries in Illinois	2,795	1,293	0.0588	0.0384	-0.01
Beneficiaries in Michigan	2,490	1,575	0.0392	0.0256	-0.01
Beneficiaries in New Jersey	2,696	4,034	0.0588	0.0384	-0.13***
Probability of ED visit	**741,511**	**715,824**	**0.4508**	**0.2948**	**-0.74****
Beneficiaries in Illinois	280,319	168,919	0.5684	0.3716	-0.29
Beneficiaries in Michigan	223,147	157,573	0.6272	0.4101	-1.01**
Beneficiaries in New Jersey	238,045	389,332	0.6076	0.3973	-1.01**
Number of ED visits	**741,511**	**715,824**	**0.0196**	**0.0128**	**-0.01†**
Beneficiaries in Illinois	280,319	168,919	0.0196	0.0128	-0.00
Beneficiaries in Michigan	223,147	157,573	0.0196	0.0128	-0.02*
Beneficiaries in New Jersey	238,045	389,332	0.0196	0.0128	-0.01†
Probability of unplanned hospitalization	**741,511**	**715,824**	**0.4116**	**0.2691**	**-0.55****
Beneficiaries in Illinois	280,319	168,919	0.5292	0.3460	-0.11
Beneficiaries in Michigan	223,147	157,573	0.5684	0.3716	-0.72*
Beneficiaries in New Jersey	238,045	389,332	0.5488	0.3588	-0.89**
Number of unplanned hospitalizations	**741,511**	**715,824**	**0.0000**	**0.0000**	**0.00**
Beneficiaries in Illinois	280,319	168,919	0.0000	0.0000	0.00
Beneficiaries in Michigan	223,147	157,573	0.0000	0.0000	-0.00
Beneficiaries in New Jersey	238,045	389,332	0.0000	0.0000	-0.01†
Probability of death	**741,511**	**715,823**	**0.1764**	**0.1153**	**-0.12†**
Beneficiaries in Illinois	280,319	168,919	0.2156	0.1410	-0.00
Beneficiaries in Michigan	223,147	157,573	0.2156	0.1410	-0.17†
Beneficiaries in New Jersey	238,045	389,331	0.2156	0.1410	-0.20†

Note: The model states included: Illinois, Michigan, or New Jersey. The comparison states included: Delaware, District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, Virginia [selected areas], or Wisconsin.

[a] Test of a difference different from 0 has less than 80 percent power (1 minus type II error).

† $p < .20$, * $p < .05$, ** $p < .01$, *** $p < .001$.

Table G.6. Statistical precision for quarterly claims denials, by quarter after model implementation

Outcome and sample	Beneficiary quarterly observations in model states	Beneficiary quarterly observations in comparison states	95% half-confidence interval	80% half-confidence interval	Observed effect
Beneficiaries with diabetic lower extremity wounds					
Number of denied HBO claims					
Q1	38,673	38,591	0.0196	0.0128	0.02*
Q2	41,471	40,796	0.0196	0.0128	0.01†
Q3	44,036	42,827	0.0000	0.0000	-0.00†
Q4	45,005	43,681	0.0000	0.0000	0.00
Q5	45,691	44,069	0.0000	0.0000	0.00
Q6	45,775	43,971	0.0000	0.0000	0.00
Proportion of HBO claims denied					
Q1	340	317	0.0392	0.0256	0.09***
Q2	240	281	0.0588	0.0384	0.16***
Q3	233	265	0.0392	0.0256	0.02
Q4	245	268	0.0392	0.0256	0.01
Q5	183	214	0.0392	0.0256	0.01
Q6	152	212	0.0392	0.0256	0.01
Beneficiaries with any included condition					
Number of denied HBO claims					
Q1	47,305	46,558	0.0196	0.0128	0.04**
Q2	50,543	49,325	0.0196	0.0128	0.02*
Q3	53,788	51,919	0.0000	0.0000	-0.01†
Q4	55,091	53,222	0.0000	0.0000	-0.01*
Q5	56,192	53,982	0.0000	0.0000	-0.01†
Q6	56,529	54,177	0.0000	0.0000	-0.01**
Proportion of HBO claims denied					
Q1	415	388	0.0392	0.0256	0.10***
Q2	339	370	0.0392	0.0256	0.13***
Q3	335	380	0.0392	0.0256	0.02
Q4	355	385	0.0392	0.0256	0.00
Q5	273	341	0.0392	0.0256	0.00
Q6	253	349	0.0392	0.0256	0.01

Note: The model states included: Illinois, Michigan, or New Jersey. The comparison states included: Delaware, District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, Virginia [selected areas], or Wisconsin.

[a] Test of a difference different from 0 has less than 80 percent power (1 minus type II error).

† $p < .20$, * $p < .05$, ** $p < .01$, *** $p < .001$.

In general, our analyses of outcomes related to HBO utilization had high statistical power, whereas some adverse outcomes, like hospitalization, had more modest statistical power. Across the analyses, certain impact estimates were statistically significant yet quite small and perhaps not substantively important. Thus, we recommend reviewing both the statistical significance and the magnitude of the impact estimates.

APPENDIX H

STATISTICAL POWER TO DETECT THE EFFECTS OF THE MODEL ON COSTS

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

In this appendix, we provide an analysis of the statistical precision for detecting effects of the HBO prior authorization program on different outcomes related to HBO service costs. Outcomes related to these costs include expenditures for HBO services, expenditures for standard therapy, and total Medicare FFS expenditures. Table H.1 presents precision estimates for the expenditure outcomes. They include separate results for beneficiaries with diabetic lower extremity wounds or beneficiaries with any included condition. See Appendix G for more information on how precision estimates are calculated.

Table H.1. Statistical precision for HBO expenditure outcomes

Outcome and sample	Beneficiary quarterly observations in model states	Beneficiary quarterly observations in comparison states	95% half-confidence interval	80% half-confidence interval	Observed effect
Beneficiaries with diabetic lower extremity wounds					
HBO expenditures	605,314	592,045	21.6968	14.1868	-58.94*** [a]
Beneficiaries in Illinois	231,155	138,833	23.3824	15.2889	-15.71† [a]
Beneficiaries in Michigan	183,603	136,897	25.6363	16.7627	-48.63*** [a]
Beneficiaries in New Jersey	190,556	316,315	25.7539	16.8396	-126.44*** [a]
HBO and standard therapy expenditures	605,314	592,045	22.8336	14.9301	-64.45*** [a]
Beneficiaries in Illinois	231,155	138,833	24.4604	15.9938	-20.75† [a]
Beneficiaries in Michigan	183,603	136,897	26.7927	17.5188	-54.56*** [a]
Beneficiaries in New Jersey	190,556	316,315	26.7143	17.4675	-131.91*** [a]
Total Medicare FFS expenditures	605,314	592,045	421.8038	275.8027	-180.12 [a]
Beneficiaries in Illinois	231,155	138,833	467.2554	305.5219	213.37 [a]
Beneficiaries in Michigan	183,603	136,897	476.3692	311.4811	-404.39†[a]
Beneficiaries in New Jersey	190,556	316,315	505.5531	330.5634	-314.30 [a]
Beneficiaries with any included condition					
HBO expenditures	741,511	715,824	20.1680	13.1872	-59.64*** [a]
Beneficiaries in Illinois	280,319	168,919	21.9712	14.3662	-16.47† [a]
Beneficiaries in Michigan	223,147	157,573	23.6568	15.4683	-54.78*** [a]
Beneficiaries in New Jersey	238,045	389,332	23.6568	15.4683	-117.45*** [a]
Total Medicare FFS expenditures	741,511	715,824	376.7051	246.3142	-235.52 [a]

Outcome and sample	Beneficiary quarterly observations in model states	Beneficiary quarterly observations in comparison states	95% half-confidence interval	80% half-confidence interval	Observed effect
Beneficiaries in Illinois	280,319	168,919	417.4919	272.9833	136.16 [a]
Beneficiaries in Michigan	223,147	157,573	424.0382	277.2637	-450.48*[a]
Beneficiaries in New Jersey	238,045	389,332	446.7346	292.1040	-350.32†[a]

Note: The model states included: Illinois, Michigan, or New Jersey. The comparison states included: Delaware, District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, Virginia [selected areas], or Wisconsin.

[a] Test of a difference different from 0 has less than 80 percent power (1 minus type II error).

† p < .20, * p < .05, ** p < .01, *** p < .001

As with the utilization estimates, we generally measured the impact estimates for cost outcomes with high precision. Only total Medicare FFS expenditures estimates were measured imprecisely, defined as confidence intervals that include zero.

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