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Policy Research

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

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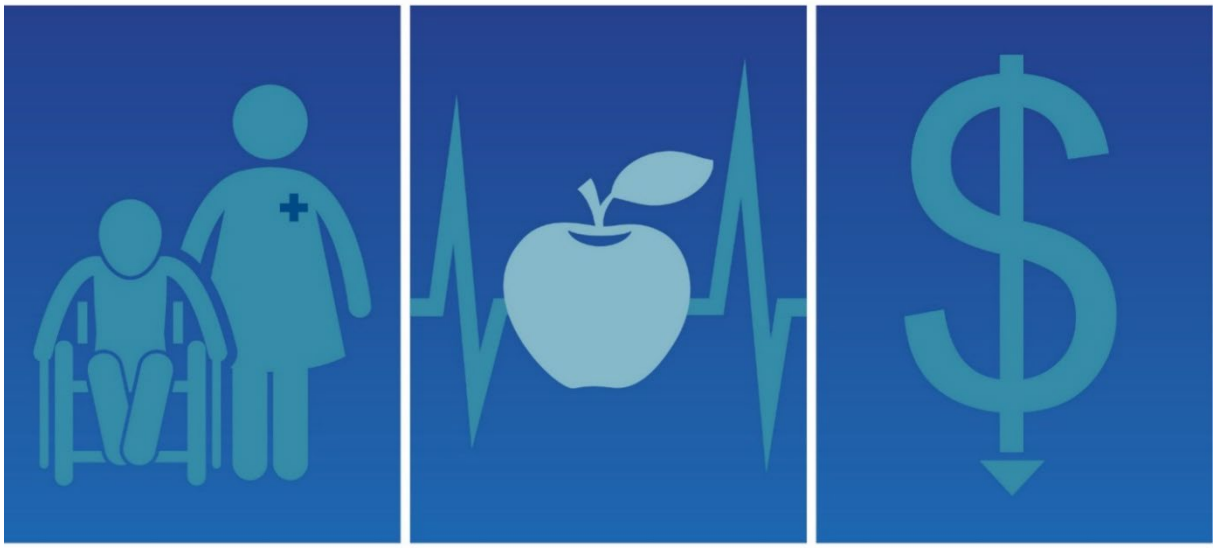

Better Care, Healthier People, Smarter Spending

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APPENDIX A

HBO COMPARISON GROUP SELECTION

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This appendix describes our approach for selecting a set of matched-comparison states.

As the report noted, the evaluation used a difference-in-differences design that estimated 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 was the choice of the comparison states, which permitted comparison with the model states. The outcomes for the comparison states were the counterfactual outcomes. Given that a well-chosen counterfactual reduces the need for the outcome analyses to depend as critically as it otherwise would upon 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 that are also correlated with the outcomes. State-level matching may control for some unobserved confounding factors, if these factors are correlated with the observed characteristics used in the matching.

To maximize the internal validity of the difference-in-differences analytic approach, we had to choose a set of comparison states that were 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 because CMS chose the states with the highest HBO service utilization and highest rates of improper claims for initial implementation of the prior authorization model.

The goal of the comparison group selection effort was to select a set of comparison states for the impact analysis that would 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 if they 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 Contractor (MAC) jurisdictions that served the model states. Because prior authorization was implemented by the MACs, states that were administered by the same MACs but were not subject to prior authorization were a natural counterfactual. These comparison states were subject to many of the same policies and administrative processes as the model states, except for prior authorization. Other MACs may have had different policies and administrative processes that could confound the impact analysis. A.1 shows the model states and comparison states by MAC.

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]

Source: CMS. "Medicare Administrative Contractors." Last updated July 2016. Available at https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/MACs-by-State-July-2016.pdf.

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

MAC = Medicare Administrative Contractor.

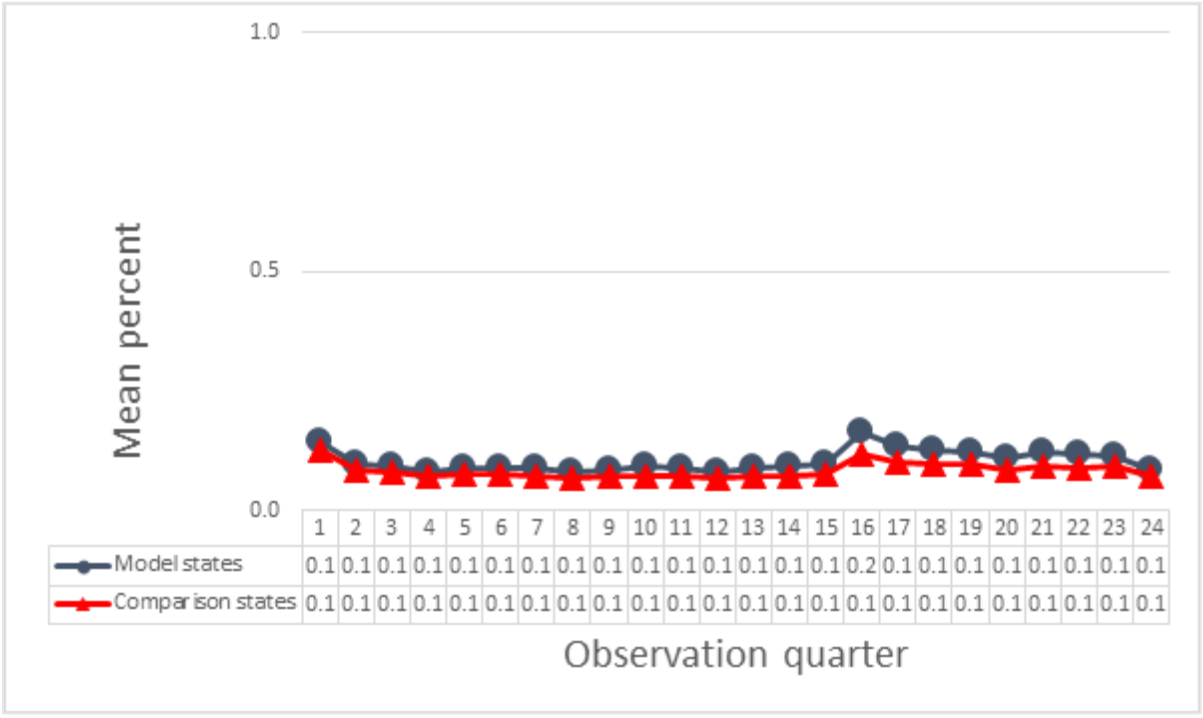
We limited the comparison states to those within the same MACs as the model states to increase the likelihood of achieving balance on unobserved characteristics related to the administration of HBO Medicare claims. The second step in our selection process involved determining how well the model and comparison states were balanced on observed factors. Figures A.1 to A.5 present several indicators related to the Medicare beneficiary population, 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 was not required because we weighted beneficiaries for the impact analysis based on a range of characteristics (see Appendix D for more details). What was important was that the model and comparison states were similar on each measure.[1]

As the figures show, the model and comparison states were well-balanced on all but one of these measures.[2] The beneficiaries in the comparison states were more likely to live in a rural area, but the difference in this measure could be reduced by 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 were well-balanced on observable characteristics. We also believe they were balanced on key unobservable characteristics because of our selection of 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 because the rates of some characteristics are extremely rare.

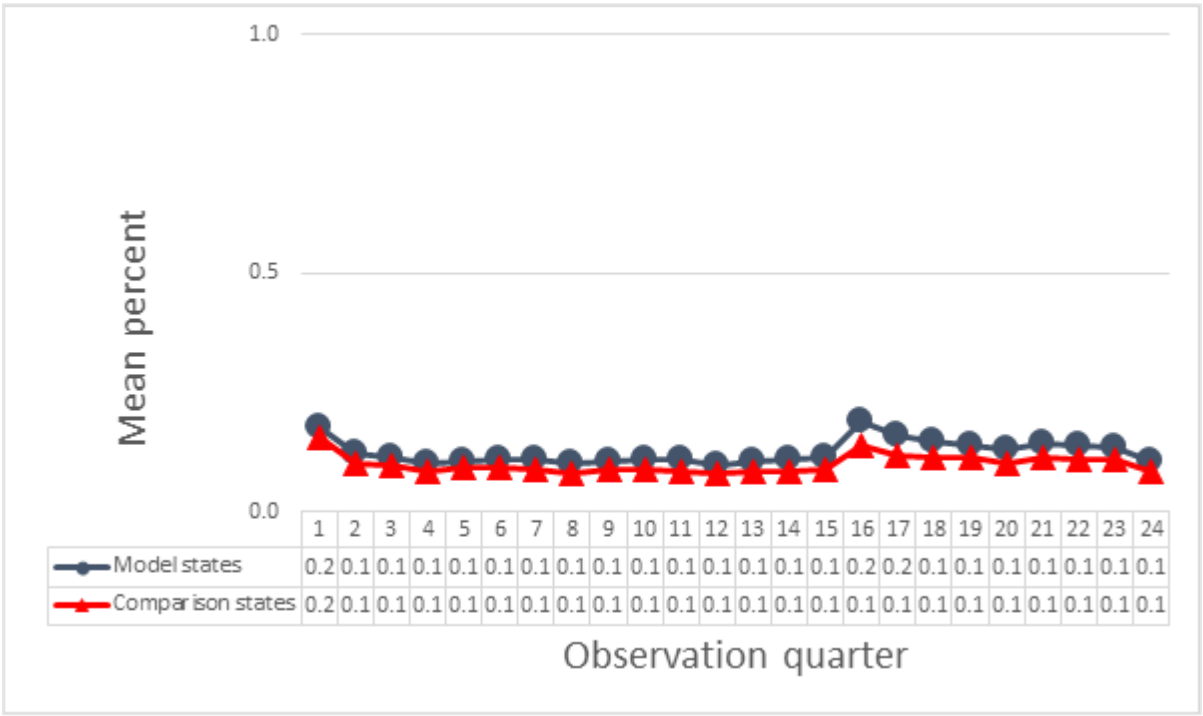
[2] The figures include all Medicare beneficiaries located in the states, regardless of medical condition or HBO treatment. We did not use these restrictions to consider the full Medicare population in the states because matching was at the state level.

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



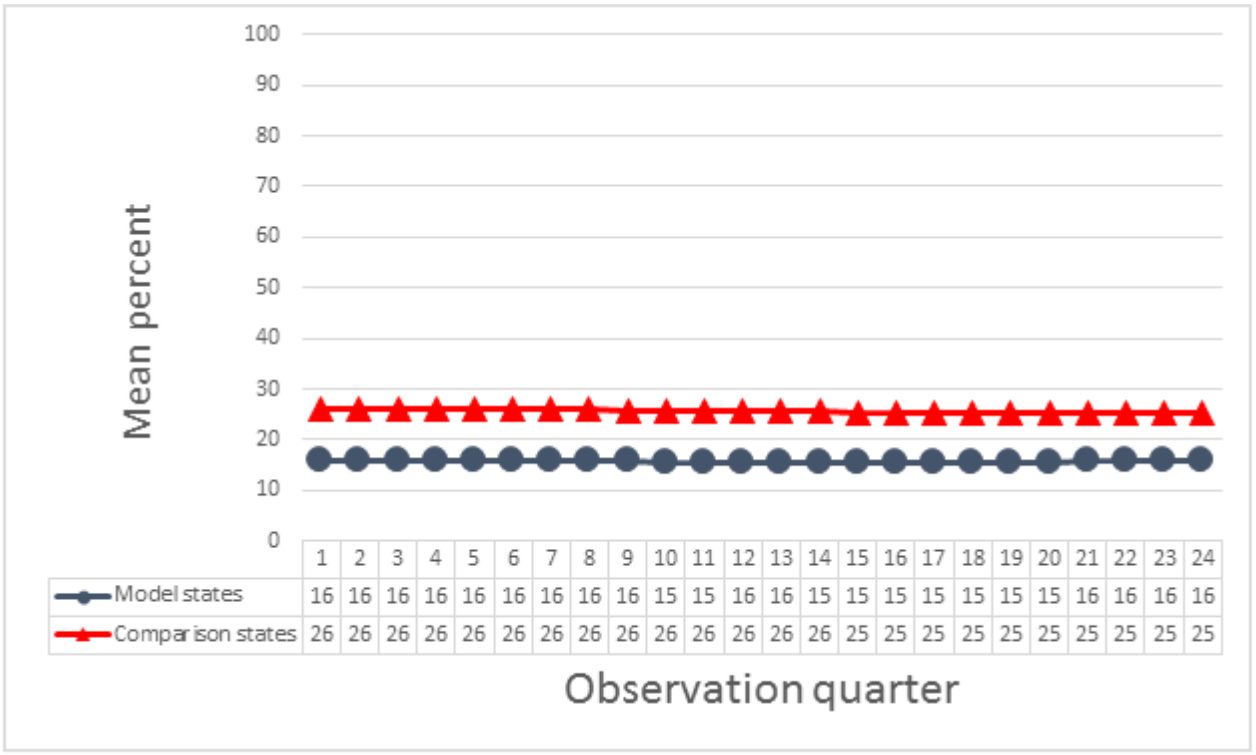
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Model states	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Comparison states	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1

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



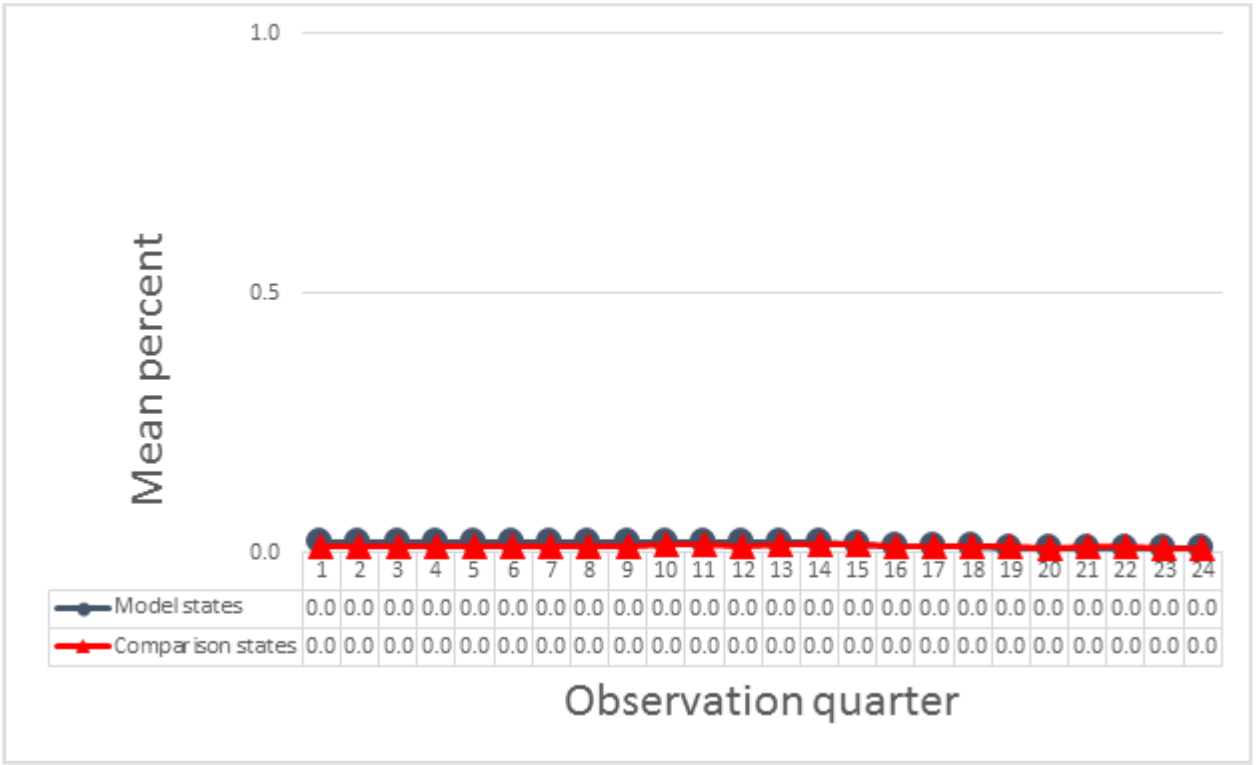
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Model states	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Comparison states	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1

Figure A.3. Mean percent of rural beneficiaries



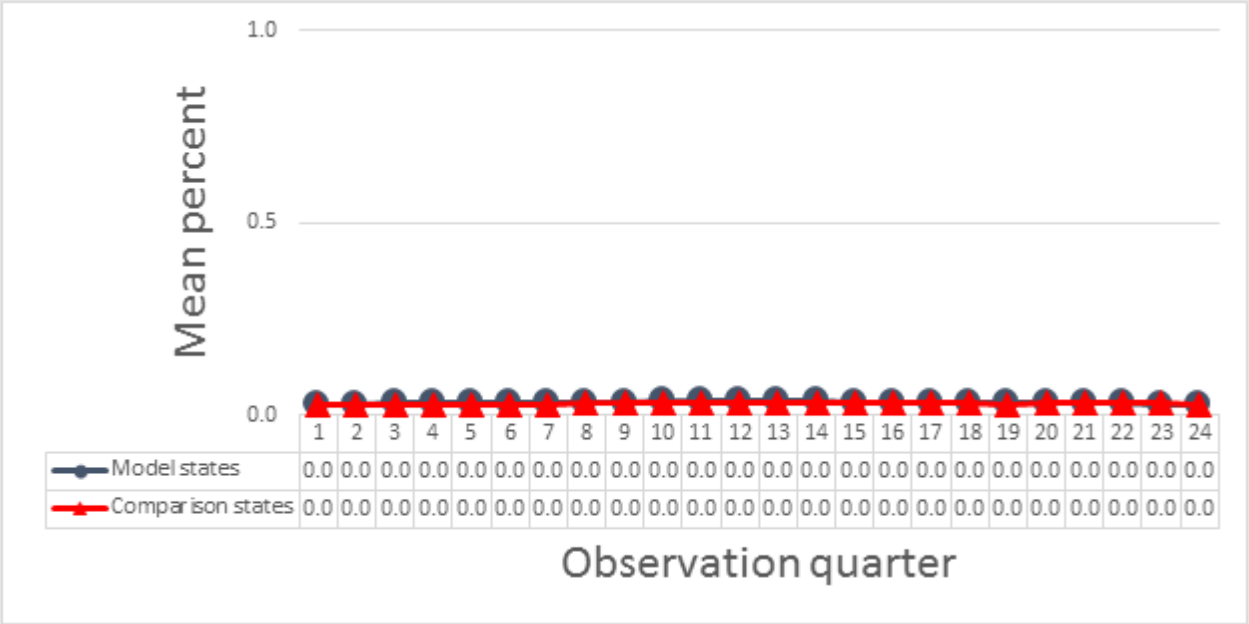
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Model states	16	16	16	16	16	16	16	16	16	15	15	16	16	15	15	15	15	15	15	15	16	16	16	16
Comparison states	26	26	26	26	26	26	26	26	26	26	26	26	26	26	25	25	25	25	25	25	25	25	25	25

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	21	22	23	24
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	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	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	21	22	23	24
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	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	0.0	0.0	0.0	0.0

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APPENDIX B

QUANTITATIVE ANALYSIS

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In this appendix, we discuss the possibility of spillover effects from model states to comparison states and describe the analyses we conducted to assess the potential threat to our evaluation design.[3] 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.

A. Is there evidence of a spillover effect?

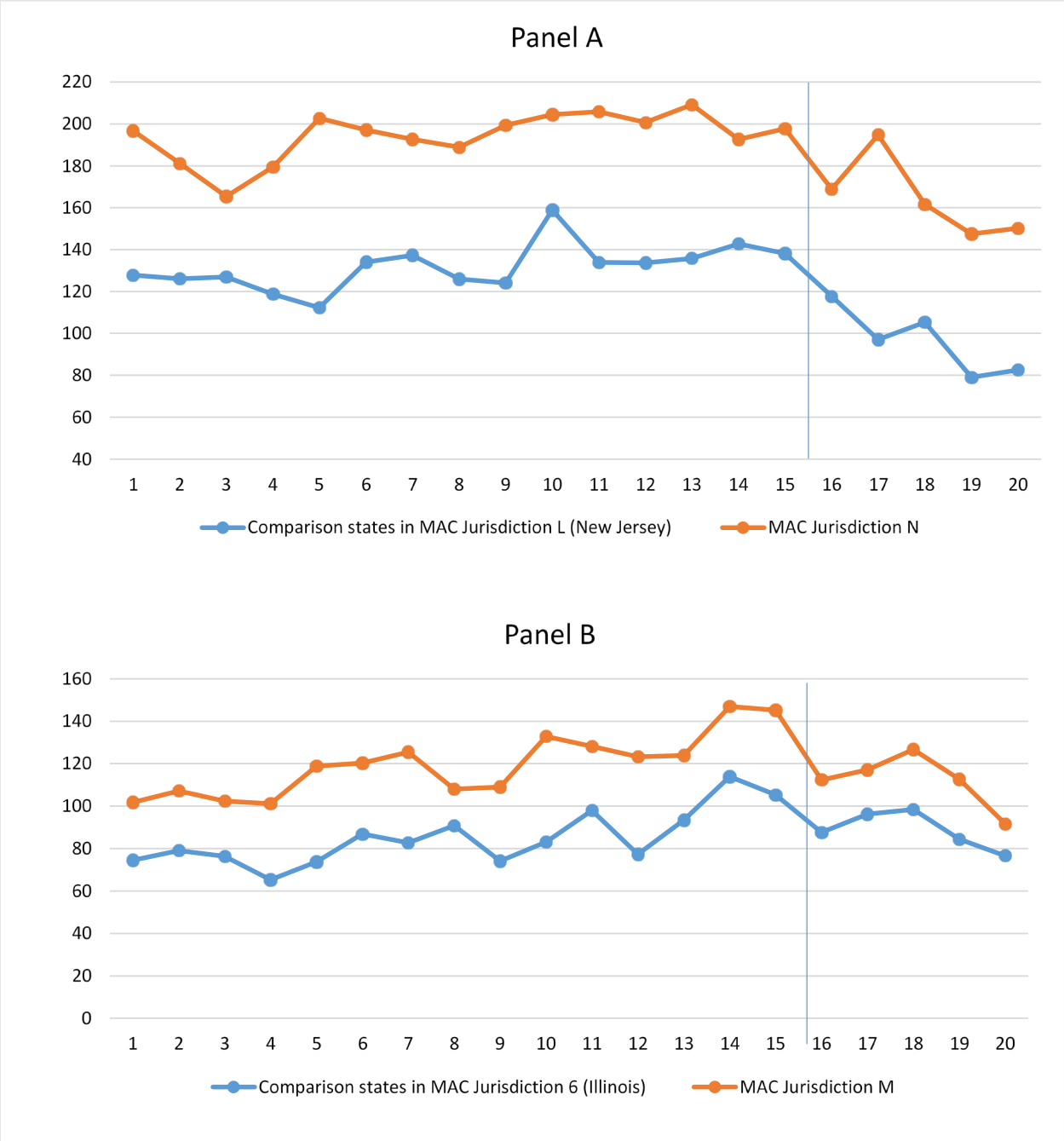
Our comparison group strategy used states that were in the same MAC jurisdiction as the model states but that were not subject to prior authorization. If claims processing for the comparison group changed as a result of the model (if, for example, claims edits or human reviewers were stricter in evaluating claims from comparison states following model implementation than previously), our regression analyses would 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 HBO utilization in the Medicare population fell noticeably in a number of MAC jurisdictions 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 the 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 Alexandria in Virginia). Similarly, we cannot rule out that changes observed in the comparison states were 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, multisite organizations—may have anticipated stricter enforcement of existing HBO requirements, which were in effect but not rigorously enforced in non-model states. These organizations may have preemptively 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 would result in our estimates being biased toward zero because the comparison states would also be influenced by the model.

[3] This analysis has not been updated since the interim report, at which point we concluded that spillover effects were not a significant threat to our design.

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



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

HBO = hyperbaric oxygen; MAC = Medicare Administrative Contractor.

B. Beneficiary summary statistics

After applying the calibration weights, beneficiaries in comparison states were similar to those in model states on nearly all of the baseline demographic and health characteristics that we examined. B.1a contains weighted summary statistics for FFS beneficiaries with diabetic lower extremity wounds in model and comparison states. The differences were 6.4 percent or less of the model group mean. B.1b contains weighted summary statistics for FFS beneficiaries with any included condition in the model and comparison states. Baseline differences were slightly larger for the group of beneficiaries with any included condition but still below 10 percent of the model group mean.

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

	Model mean (SD)	Comparison mean (SD)	Difference	Percentage difference (%)
Age (years)	71.4 (12.2)	71.1 (12.5)	0.3***	0.4
Female (%)	43.2 (49.5)	42.8 (49.5)	0.5	1.1
Race (%)				
White	77.0 (42.1)	77.1 (42.0)	-0.1	-0.2
Black	18.6 (38.9)	18.5 (38.9)	0.01	0.04
Other	4.5 (20.7)	4.4 (20.4)	0.1	2.9
Rural (%)	13.7 (34.4)	14.0 (34.7)	-0.3	-2.2
Dual (%)	29.3 (45.5)	29.6 (45.7)	-0.3	-1.0
HCC score	4.5 (2.6)	4.2 (2.3)	0.3***	6.4
Number of beneficiaries	**86,354**	**83,224**		

Note: The table presents weighted means (and standard deviations) of beneficiary characteristics for beneficiaries with diabetic lower extremity wounds on dates of service from April 2012 through December 2017. Comparison group individuals were weighted to resemble model group individuals on baseline demographic and health characteristics.

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

HCC = Hierarchical Condition Category.

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

	Model mean (SD)	Comparison mean (SD)	Difference	Percentage difference (%)
Age (years)	71.3 (12.5)	71.0 (12.9)	0.3***	0.5
Female (%)	43.3 (49.5)	42.8 (49.5)	0.5 *	1.2
Race (%)				
White	77.7 (41.6)	77.6 (41.7)	0.09	0.1
Black	17.9 (38.3)	18.2 (38.6)	-0.3	-1.8
Other	4.4 (20.5)	4.2 (19.9)	0.2	5.1
Rural (%)	13.7 (34.4)	13.9 (34.6)	-0.2	-1.8
Dual (%)	28.6 (45.2)	29.2 (45.5)	-0.6*	-1.9
HCC score	4.4 (2.6)	4.2 (2.4)	0.2***	5.3
Included condition (%)				
Diabetic lower extremity wounds	81.4 (38.9)	79.9 (40.1)	1.5***	1.8
Osteomyelitis	14.1 (34.8)	15.4 (36.1)	-1.3***	-9.3
Irradiation cystitis	3.0 (17.0)	3.2 (17.5)	-0.2*	-6.7
Soft tissue radionecrosis	4.1 (19.8)	4.3 (20.3)	-0.2*	-5.4
Osteoradionecrosis	2.5 (15.5)	2.7 (16.1)	-0.2*	-8.1
Actinomycosis	1.5 (12.3)	1.6 (12.4)	-0.04	-2.5
Number of beneficiaries	**106,113**	**101,656**		

Note: The table presents weighted means (and standard deviations) of beneficiary characteristics for beneficiaries with any included condition on dates of service from April 2012 through December 2017. Comparison group individuals were weighted to resemble model group individuals on baseline demographic and health characteristics.

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

HCC = Hierarchical Condition Category.

C. 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 that we examined. Before the model was implemented, beneficiaries in model states had higher quarterly utilization of and expenditures on HBO services. They also had higher total Medicare FFS expenditures.

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

	Model mean (SD)	Comparison mean (SD)	Difference	Percent difference (%)
Probability of HBO utilization (%)	1.9 (13.8)	1.5 (12.2)	0.4***	21.8
Number of HBO treatments	0.39 (3.46)	0.27 (2.75)	0.11***	29.4
HBO expenditures ($)	169 (1,526)	117 (1,229)	51***	30.5
Total Medicare FFS expenditures ($)	15,847 (27,070)	13,881 (24,989)	1,967***	12.4
Number of observations	**259,539**	**263,507**		

Note: The table presents baseline weighted means (and standard deviations) of quarterly beneficiary utilization and payment outcomes for beneficiaries with diabetic lower extremity wounds on dates of service from April 2012 through December 2017. Comparison group individuals were weighted to resemble model group individuals on baseline demographic and health characteristics.

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

FFS = fee-for-service; HBO = hyperbaric oxygen.

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

	Model mean (SD)	Comparison mean (SD)	Difference	Percent difference (%)
Probability of HBO utilization (%)	2.0 (13.8)	1.6 (12.5)	0.4***	19.3
Number of HBO treatments	0.40 (3.49)	0.29 (2.85)	0.11***	26.7
HBO expenditures ($)	173 (1,545)	124 (1,270)	48***	28.0
Total Medicare FFS expenditures ($)	15,216 (26,693)	13,646 (25,436)	1,570***	10.3
Number of observations	**321,782**	**319,567**		

Note: The table presents baseline weighted means (and standard deviations) of quarterly beneficiary utilization and payment outcomes for beneficiaries with diabetic lower extremity wounds on dates of service from April 2012 through December 2017. Comparison group individuals were weighted to resemble model group individuals on baseline demographic and health characteristics.

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

FFS = fee-for-service; HBO = hyperbaric oxygen.

Tables B.3a and B.3b show our estimates of the impact of prior authorization stratified by rural residence and by dual eligibility for Medicare and Medicaid. Utilization and cost impacts were larger among rural than urban beneficiaries in both diagnosis groups. Also among both diagnosis groups, impacts were larger among non-dual eligible beneficiaries than among dual eligible beneficiaries.

B.3a. 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)	HBO expenditures ($) (III)	Total Medicare FFS expenditures ($) (VI)
Rural status				
Rural				
Average marginal effect	-0.2*	-0.02	-29	158
(Standard error)	(0.1)	(0.04)	(19)	(338)
Baseline	1.9	0.37	154	11,770
Change from baseline (%)	-12.6	-6.4	-19.1	1.3
R^2	0.08	0.01	0.01	0.24
Not rural				
Average marginal effect	-0.3***	-0.10***	-64***	226
(Standard error)	(0.04)	(0.02)	(12)	(211)
Baseline	1.9	0.39	171	16,508
Change from baseline (%)	-16.5	-26.2	-37.4	1.4
R^2	0.07	0.01	0.01	0.28
Dual eligibility				
Dual eligible				
Average marginal effect	-0.2*	-0.05**	-41*	310
(Standard error)	(0.07)	(0.02)	(16)	(365)
Baseline	1.5	0.28	123	19,183
Change from baseline (%)	-9.9	-19.0	-33.1	1.6
R^2	0.06	0.01	0.003	0.28
Not dual eligible				
Average marginal effect	-0.4***	-0.12***	-67***	167
(Standard error)	(0.05)	(0.02)	(13)	(210)
Baseline	2.1	0.43	189	14,319
Change from baseline (%)	-17.9	-28.7	-35.3	1.2
R^2	0.08	0.01	0.01	0.26

Note: The table presents average marginal effects and (standard errors) from weighted logistic (I), negative binomial (II), and OLS (III and IV) regression analyses using 217,694 rural and 1,173,416 non-rural beneficiary-quarters and 420,272 dual and 970,838 non-dual beneficiary-quarters for beneficiaries with diabetic lower extremity wounds on dates of service from April 2012 through December 2017. Control variables included age, age squared, sex, race, and HCC score. Standard errors were 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.

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

FFS = fee-for-service; HBO = hyperbaric oxygen; HCC = Hierarchical Condition Category; OLS = ordinary least squares.

B.3b. 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)	HBO expenditures ($) (III)	Total Medicare FFS expenditures ($) (VI)
Rural status				
Rural				
Average marginal effect	-0.2*	-0.12*	-24	339
(Standard error)	(0.1)	(0.06)	(19)	(310)
Baseline	1.9	0.39	160	11,506
Change from baseline (%)	-10.6	-29.7	-14.9	3.0
R^2	0.10	0.02	0.01	0.24
Not rural				
Average marginal effect	-0.4***	-0.14***	-61***	157
(Standard error)	(0.04)	(0.02)	(11)	(190)
Baseline	2.0	0.40	175	15,813
Change from baseline (%)	-17.9	-35.1	-34.9	1.0
R^2	0.10	0.02	0.01	0.27
Dual eligibility				
Dual eligible				
Average marginal effect	-0.2**	-0.07**	-39*	220
(Standard error)	(0.06)	(0.02)	(16)	(337)
Baseline	1.6	0.29	125	18,646
Change from baseline (%)	-10.8	-25.3	-31.3	1.2
R^2	0.09	0.02	0.01	0.27
Not dual eligible				
Average marginal effect	-0.4***	-0.20***	-63***	180
(Standard error)	(0.05)	(0.04)	(12)	(186)
Baseline	2.1	0.44	194	13,721
Change from baseline (%)	-19.1	-44.9	-32.7	1.3
R^2	0.10	0.02	0.01	0.26

Note: The table presents average marginal effects and (standard errors) from weighted logistic (I), negative binomial (II), and OLS (III and IV) regression analyses using 262,158 rural and 1,434,061 non-rural beneficiary-quarters and 497,287 dual and 1,198,932 non-dual beneficiary-quarters for beneficiaries with any included condition from dates of service from April 2012 through December 2017. Control variables included age, age squared, sex, race, and HCC score. Standard errors were 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.

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

FFS = fee-for-service; HBO = hyperbaric oxygen; HCC = Hierarchical Condition Category; OLS = ordinary least squares.

D. Quality of care and adverse outcomes

Tables B.4a, B.4b, and B5 show the baseline levels of the quality of care and adverse outcome measures per beneficiary per quarter for the beneficiary population that we examined. Before the model was implemented, beneficiaries in model states had higher rates of these outcomes, although the differences were often small in magnitude.

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

	Model mean (SD)	Comparison mean (SD)	Difference	Percentage difference (%)
Proportion of HBO treatments with physician supervision	0.9 (0.2)	0.9 (0.2)	0.01	0.6
Probability of emergency department visit (%)	38.9 (48.7)	36.5 (48.2)	2.4***	6.0
Number of emergency department visits	0.69 (1.28)	0.64 (1.28)	0.05***	7.2
Probability of unplanned hospitalization (%)	31.3 (46.4)	28.4 (45.1)	2.9***	9.4
Number of unplanned hospitalizations	0.46 (0.89)	0.40 (0.82)	0.05***	11.7
Probability of death (%)	5.4 (22.5)	5.0 (21.7)	0.4***	7.7
Number of observations	**259,539**	**263,507**		

Note: The table presents baseline weighted means (and standard deviations) of quarterly beneficiary quality of care and adverse outcomes for beneficiaries with diabetic lower extremity wounds on dates of service from April 2012 through December 2017. Comparison group individuals were weighted to resemble model group individuals on baseline demographic and health characteristics.

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

HBO = hyperbaric oxygen.

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

	Model mean (SD)	Comparison mean (SD)	Difference	Percentage difference (%)
Proportion of HBO treatments with physician supervision	0.9 (0.2)	0.9 (0.2)	0.0	0.3
Probability of emergency department visit (%)	37.6 (48.5)	35.7 (47.9)	1.9***	5.1
Number of emergency department visits	0.66 (1.26)	0.62 (1.27)	0.04***	6.0
Probability of unplanned hospitalization (%)	30.3 (46.0)	27.9 (44.9)	2.4***	8.0
Number of unplanned hospitalizations	0.44 (0.87)	0.39 (0.82)	0.04***	10.2
Probability of death (%)	5.2 (22.2)	4.9 (21.6)	0.3***	5.0
Number of observations	**321,782**	**319,567**		

Note: The table presents baseline weighted means (and standard deviations) of quarterly beneficiary quality of care and adverse outcomes for beneficiaries with any included condition on dates of service from April 2012 through December 2017. Comparison group individuals were weighted to resemble model group individuals on baseline demographic and health characteristics.

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

HBO = hyperbaric oxygen.

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

	Model mean (SD)	Comparison mean (SD)	Difference	Percentage difference (%)
Probability of emergency department visit for lower extremity wound (%)	0.5 (7.2)	0.5 (7.2)	0.0004	0.1
Number of emergency department visits for lower extremity wound	0.01 (0.08)	0.01 (0.08)	0.0001	2.2
Probability of unplanned hospitalization for lower extremity wound (%)	0.3 (5.7)	0.3 (5.2)	0.05**	15.2
Number of unplanned hospitalizations for lower extremity wound	0.003 (0.06)	0.003 (0.06)	0.0005**	15.3
Probability of amputation (%)	2.5 (15.6)	2.9 (16.7)	-0.4***	-15.3
Number of observations	**259,539**	**263,507**		

Note: The table presents baseline weighted means (and standard deviations) of quarterly beneficiary adverse outcomes related to diabetic lower extremity wounds on dates of service from April 2012 through December 2017. Comparison group individuals were weighted to resemble model group individuals on baseline demographic and health characteristics.

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

Tables B.6a and B.6b show our estimates of the impact of prior authorization stratified by rural residence and by dual eligibility for Medicare and Medicaid. Impacts were similar among rural and urban beneficiaries in both the group with any included condition and the subgroup with diabetic leg wounds. The estimated impacts moved in opposite directions for dual eligible (positive) and non-dual eligible beneficiaries (negative), although the estimates were small in magnitude and percentage for both subgroups and only statistically significant for non-dual eligible beneficiaries.

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	-0.4	-0.02	-0.5	-0.01	-0.2
(Standard error)	(0.02)	(0.4)	(0.01)	(0.3)	(0.01)	(0.2)
Baseline	1.0	36.5	0.66	27.3	0.38	4.7
Change from baseline (%)	-1.3	-1.2	-3.7	-2.0	-1.5	-3.2
R^2	0.04	0.12	0.07	0.18	0.12	0.10
Not rural						
Average marginal effect	-0.04	-0.6**	-0.00	-0.3	-0.00	-0.1
(Standard error)	(0.02)	(0.2)	(0.01)	(0.2)	(0.00)	(0.1)
Baseline	0.9	37.8	0.66	30.8	0.45	5.3
Change from baseline (%)	-4.8	-1.6	-0.6	-1.0	-0.2	-1.6
R^2	0.03	0.14	0.09	0.19	0.13	0.11
Dual eligibility						
Dual eligible						
Average marginal effect	-0.02	-0.1	0.02	0.4	0.01	-0.3*
(Standard error)	(0.05)	(0.4)	(0.01)	(0.3)	(0.01)	(0.2)
Baseline	0.9	45.8	0.90	36.3	0.55	5.9
Change from baseline (%)	-2.7	-0.3	2.4	1.0	1.9	-5.6
R^2	0.03	0.12	0.07	0.18	0.11	0.09
Not dual eligible						
Average marginal effect	-0.04	-0.8***	-0.02**	-0.7***	-0.01*	0.01
(Standard error)	(0.02)	(0.2)	(0.01)	(0.2)	(0.00)	(0.1)
Baseline	0.9	34.1	0.56	27.8	0.39	4.9
Change from baseline (%)	-4.0	-2.4	-3.2	-2.4	-1.9	0.3
R^2	0.03	0.14	0.09	0.19	0.13	0.12

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 262,158 rural and 1,434,061 non-rural beneficiary-quarters and 497,287 dual and 1,198,932 non-dual beneficiary-quarters for beneficiaries with any included condition on dates of service from April 2012 through December 2017. Control variables included age, age squared, sex, race, and HCC score. Standard errors were 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.

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

HBO = hyperbaric oxygen; HCC = Hierarchical Condition Category; OLS = ordinary least squares.

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	-0.4	-0.02	-0.5	-0.01	-0.4*
(Standard error)	(0.03)	(0.5)	(0.01)	(0.4)	(0.01)	(0.2)
Baseline	1.0	37.5	0.68	28.0	0.39	4.9
Change from baseline (%)	-2.7	-1.0	-3.3	-1.9	-2.1	-8.0
R^2	0.04	0.12	0.08	0.18	0.12	0.09
Not rural						
Average marginal effect	-0.05	-0.5*	-0.00	-0.2	0.00	-0.2
(Standard error)	(0.03)	(0.2)	(0.01)	(0.2)	(0.00)	(0.1)
Baseline	0.9	39.1	0.69	31.9	0.47	5.5
Change from baseline (%)	-6.0	-1.3	-0.5	-0.6	0.5	-2.8
R^2	0.03	0.14	0.08	0.19	0.12	0.10
Dual eligibility						
Dual eligible						
Average marginal effect	-0.01	0.2	0.02	0.6	0.02*	-0.5**
(Standard error)	(0.1)	(0.4)	(0.02)	(0.3)	(0.01)	(0.2)
Baseline	0.9	46.6	0.92	37.0	0.57	6.1
Change from baseline (%)	-1.1	0.4	2.7	1.7	3.3	-7.4
R^2	0.03	0.13	0.07	0.18	0.11	0.09
Not dual eligible						
Average marginal effect	-0.1*	-0.9***	-0.02**	-0.7***	-0.01*	-0.1
(Standard error)	(0.03)	(0.2)	(0.01)	(0.2)	(0.00)	(0.1)
Baseline	0.9	35.3	0.58	28.8	0.41	5.0
Change from baseline (%)	-6.2	-2.4	-3.2	-2.4	-2.0	-1.2
R^2	0.04	0.14	0.08	0.19	0.13	0.11

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 217,694 rural and 1,173,416 non-rural beneficiary-quarters and 420,272 dual and 970,838 non-dual beneficiary-quarters for beneficiaries with diabetic lower extremity wounds on dates of service from April 2012 through December 2017. Control variables included age, age squared, sex, race, and HCC score. Standard errors were 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.

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

HBO = hyperbaric oxygen; HCC = Hierarchical Condition Category; OLS = ordinary least squares.

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APPENDIX C

QUANTITATIVE METHODS

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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.

A. Selection of conditions

Using the population of individuals in the three model 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 from 2012 to 2017, we selected beneficiaries who were diagnosed with one of the conditions for which prior authorization was required in order 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 by using the 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 HBO 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.

B. Outcomes

We considered several quarterly outcomes related to utilization and cost, quality of care and adverse outcomes, and denied claims. 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 fell into two categories:

1. **HBO service utilization.** Claims for HBO therapy (identified by using HCPCS code 1300 before January 1, 2015, and HCPCS code G0277 after January 1, 2015) with or without physician supervision (identified by using HCPCS code 99183).
2. **HBO service utilization with other treatment.** Claims for HBO therapy with an appropriate history of standard wound therapy, as required in Medicare's NCD.

We also calculated total Medicare FFS 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 with a condition that required prior authorization. These outcome measures are presented in C.1. Quality and adverse outcome measures included (1) receipt of HBO with physician supervision; (2) 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); (3) amputations among beneficiaries with diabetic lower extremity wounds; and (4) death. For all utilization measures, we considered both the likelihood of receiving any service in the quarter and the number of services received. The likelihood of receiving any service was represented as a binary variable equal to 1 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 impacted the number of individuals who received services, the average number of services received by individuals, or both.

C.1. Outcome measures used in quantitative analyses

Measure	Beneficiaries with diabetes and lower extremity wound	All beneficiaries with a condition requiring prior authorization
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 FFS expenditures	✓	✓
Quality of care and adverse outcomes		
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	✓	✓
Claim denials		
Denied claims		
HBO claim denial (proportion of HBO claims denied)	✓	✓

FFS = fee-for-service; HBO = hyperbaric oxygen.

To determine what constituted an 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) consulted with physicians and other representatives from Novitas, the MAC for New Jersey. The Medicare national coverage determination (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, the MACs reviewed documentation and medical records prepared by the requesting physician. In constructing our measures of appropriate standard wound therapy, we were limited to what could be determined from Medicare administrative data. Although 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 included only these three services.

Other forms of standard wound therapy may or may not generate claims. Off-loading 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 by 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 that was identified as a set in which the gap between successive HBO 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 failed to reliably capture receipt of standard wound therapy prior to HBO treatment. As a consequence, we were unable to gauge the impact of prior authorization on the likelihood of receiving the required course of standard wound care services before starting HBO therapy.

C. Procedure codes used to create outcome measures

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.

C.2. Codes identifying history of standard therapy

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 20 cm/<
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–A656	Specialty absorptive dressing
A6257–A6259	Transparent film
A6260	Wound cleansers
A6261	Wound filler, gel/paste, per fluid ounce, not otherwise specified
A6262	Wound filler, dry form, per gram, not otherwise specified

Code	Description
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 substitutes	
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
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 matrix
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
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

Code	Description
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 (e.g., 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 (e.g., 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, revasc, endovasc, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with
37228	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 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
37231	performed

Code	Description
37232	Revasc, endovasc, open or percutaneous, tibial/peroneal artery, unilateral, each addtl vessel; with transluminal angioplasty (list separately in addition to code for primary procedure)
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
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

Code	Description
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%
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

Code	Description
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
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

Code	Description
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

Note: This table includes the code descriptions as they are found in the CMS documentation available at https://www.cms.gov/medicare-coveraGE-database/downloads/downloadable-databases.aspx, including the abbreviations and units of measurement.

We identified codes for amputation of the lower extremity in the same way we identified standard wound therapy services (see C.3), through literature review and in consultation with Mathematica, industry, and Novitas physicians. We limited our 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.

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 (e.g., Syme, Pirogoff type)
27889	Ankle disarticulation
28800	Amputation, foot; midtarsal (e.g., Chopart type procedure)
28805	Amputation, transmetatarsal
28810	Metatarsal with toe, single
28820	Metatarsophalangeal joint
28825	Interphalangeal joint

Note: This table includes the code descriptions as they are found in the CMS documentation available at https://www.cms.gov/medicare-coveraGE-database/downloads/downloadable-databases.aspx, including the abbreviations and units of measurement.

D. 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—was that the health characteristics of the study population changed over time. Only beneficiaries with active conditions appeared in the early quarters because their diagnoses drew them into the population. Beneficiaries with new diagnoses were added over time, but beneficiaries whose conditions first appeared in 2012 or 2013 stayed in the sample, possibly for several years after their conditions resolved. Utilization and expenditure patterns therefore changed over time, as the proportion of the population actively experiencing one of the included medical conditions decreased.

Although our DID approach (described below) controlled 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 made it difficult to visually detect departures from the trend in figures. We therefore developed figures showing trends in utilization and expenditures[4] by limiting each individual's contribution to the sample to the four quarters following his or her date of diagnosis. Although it was important to observe outcomes over time (especially for adverse events), observing individuals in just the year following their diagnosis allowed us to capture HBO utilization and expenditures at the time they were most likely incurred and gave us a comparable population in each quarter of individuals who were diagnosed in the previous year. The vast majority of beneficiaries who received HBO had their first treatment within one year of the first time a diagnosis for an included condition appeared in their claim record.

[4] These are presented in Chapter III, Quantitative Analysis Results.

E. Regression methods

We used the following as our main model:

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

where Y_{ist} was the outcome for beneficiary *i* in state *s* in quarter *t*; I_s and I_t were state and quarter fixed effects, respectively (omitting one indicator from each group); D_{st} took value 1 in states and quarters when the model was in effect, and 0 otherwise; and X_{ist} was a set of control variables at the beneficiary-quarter level. Controls included age; age squared; HCC 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.[5] The coefficient of interest was β, which gave the estimated per beneficiary per quarter impact of residing in a model state after the prior authorization model was implemented. *F(x)* was a function that determined whether the regression model was 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 resembled Equation (1), except that there were 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 the MACs fully implemented the prior authorization model or if it took some time for providers to become accustomed to strict adherence to preexisting documentation requirements enforced under the model. The flexible post-period model specification also resembled Equation (1), except that each sequential quarter after the model went into effect had its own β term. We identified quarters after implementation, accounting for the fact that Michigan began requiring prior authorization for HBO before Illinois and New Jersey did. Therefore, the first quarter after implementation was Quarter 14 for Michigan but Quarter 15 for Illinois and New Jersey.[6]

[5] 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.

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

APPENDIX D

HBO BENEFICIARY WEIGHTING

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This appendix describes the approach we used to balance the model and comparison state data in the study and our results. It is divided into three sections:

- The definition of included beneficiaries and an examination of covariate balance
- The approach used to generate the propensity score weights
- The choice of an adjustment approach

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 within the same MACs (Delaware, District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, Virginia [selected areas], or Wisconsin) and be at least 20 years old. In addition, beneficiaries had to have at least one inpatient visit or two outpatient visits within 90 days of each other related to one of the following diagnoses: (1) diabetic ulcers of the lower extremities, (2) osteomyelitis, (3) soft tissue radionecrosis, (4) osteoradionecrosis, or (5) actinomycosis. D.1 shows the resulting number of beneficiaries included in the model and comparison states.

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

	Model states	Matched comparison states
2012	18,778	18,430
2013	31,556	30,392
2014	41,509	39,767
2015	52,580	50,503
2016	65,209	62,395
2017	72,193	70,471

Note: The numbers increased each year because beneficiaries were included in all subsequent quarters after the quarter in which they were initially identified for inclusion, unless they died. Thus, all beneficiaries identified in 2012 who were alive in 2013 were also included in the 2013 numbers, and so on. The model states included Illinois, Michigan, and New Jersey. The comparison states included Delaware, District of Columbia, Indiana, Maryland, Minnesota, Pennsylvania, Virginia (selected areas), and 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: (1) age, (2) rural location, (3) gender, (4) race, and (5) 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 the comparison state samples. On average across all 24 observed quarters, about 81 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. About 76 percent of model state sample beneficiaries were white versus 80 percent for comparison state sample beneficiaries. We found a moderate difference in the percentage of beneficiaries in model states who lived in rural areas, 14 percent, compared with about 17 percent in comparison states. We found very small differences in the percentages of female beneficiaries and those with the other four diagnoses besides diabetic ulcers of the lower extremities. We present all of these differences, across all 24 quarters, in Figures D.1 to D.5.

B. Propensity score weighting approach

To adjust for the cited differences above, we used an inverse propensity score weighting approach, which involved two steps.[7] First, for each quarter of data we estimated a logistic regression that predicted treatment status (living in a model or a comparison state) based on the following set of characteristics: (1) beneficiary age; (2) whether the person lived in a rural area; (3) gender; (4) race (with separate indicators for black, white, Hispanic, or other); (5) whether the person was dually eligible for Medicare and Medicaid; and (6) 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 represented the likelihood that the beneficiary resided in a state with prior authorization (Rosenbaum and Rubin 1983). Each model used a single quarter of data for a single MAC; the resulting propensity score weights therefore balanced the model and comparison beneficiaries in each quarter within each MAC and for the combination of all MACs. The second stage of this process involved calculating weights (ω) for each beneficiary, which was defined as

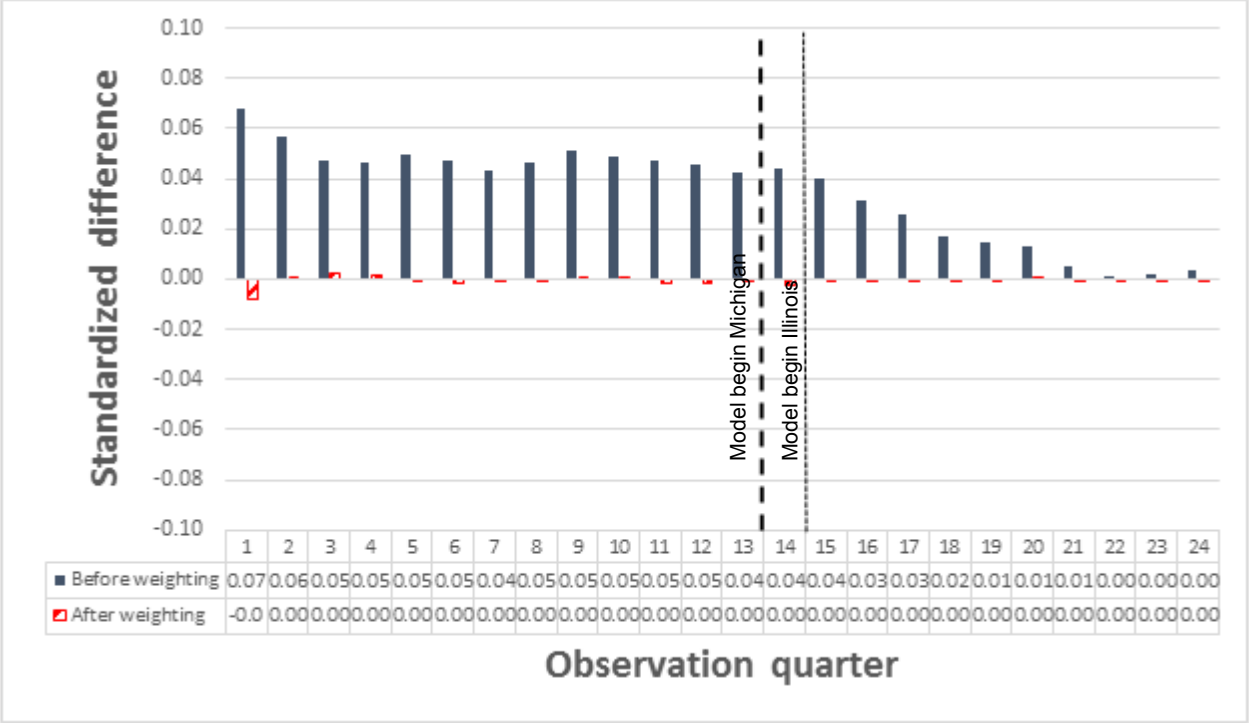
$$\omega(W,x) = W + (1-W)\frac{\hat{e}(x)}{1-\hat{e}(x)}$$

where $W = 1$ if a beneficiary lived in a model state and $W = 0$ if a beneficiary lived in a comparison state, x represented the set of characteristics included in the propensity score model, and $\hat{e}(x)$ represented the estimated propensity score (Guo and Fraser 2009). These propensity score weights reduced 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.

Figures D.1 to D.5 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 was 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. D.2 presents the yearly percent averages of each characteristic before and after the weights were applied. Generally speaking, there was already good balance on most measures, but the table and figures show a consistently effective reduction and near elimination of any existing imbalance on the key characteristics.

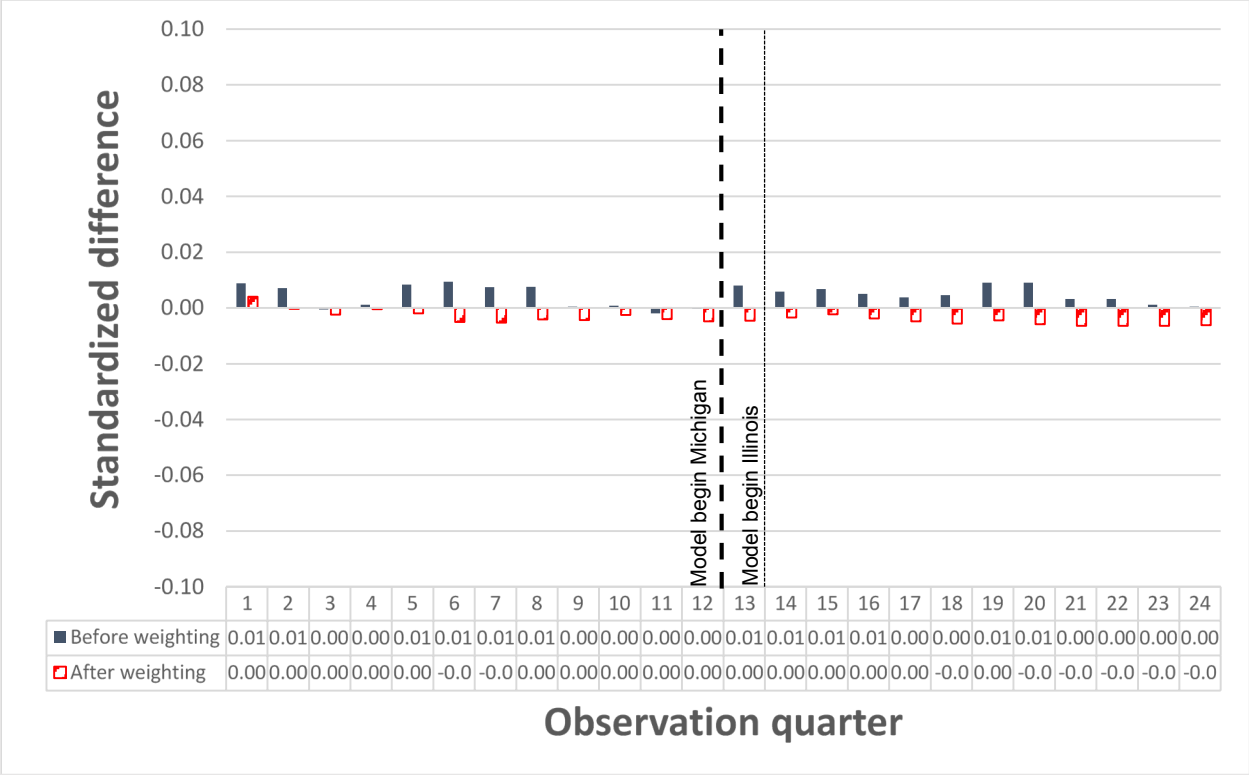
[7] We initially tried an optimal matching approach that involved calculating distances between each model state and comparison state beneficiary, then matching comparison beneficiaries to intervention beneficiaries with the smallest distance between them. However, we were unable to achieve desired balance 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, the optimal matching approach did not present a viable option for balancing model and comparison state beneficiaries.

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



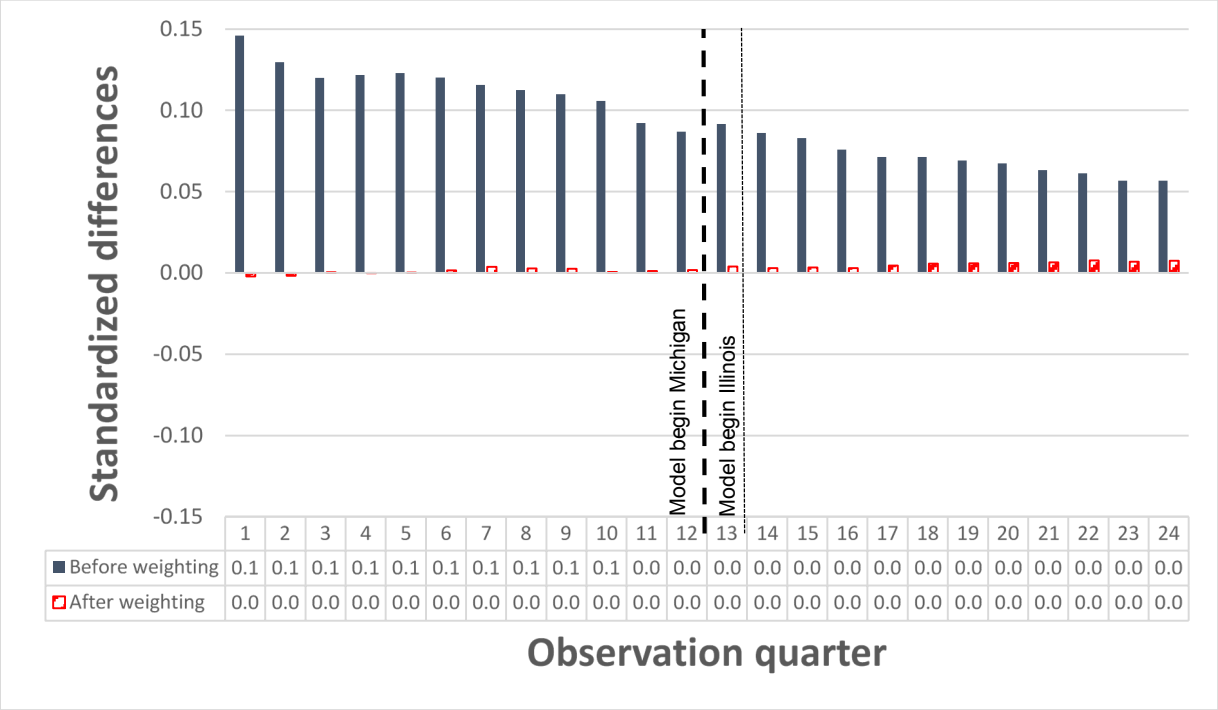
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Before weighting	0.07	0.06	0.05	0.05	0.05	0.05	0.04	0.05	0.05	0.05	0.05	0.05	0.04	0.04	0.04	0.03	0.03	0.02	0.01	0.01	0.01	0.00	0.00	0.00
After weighting	-0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

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



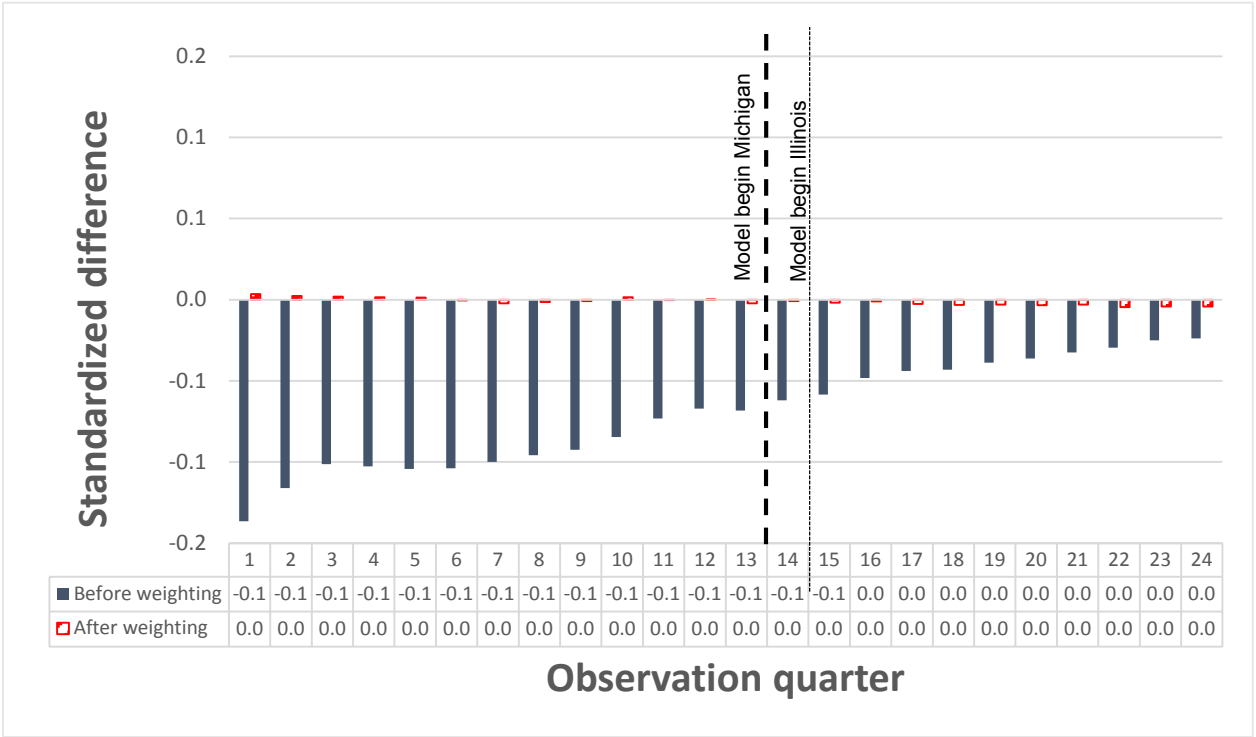
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Before weighting	0.01	0.01	0.00	0.00	0.01	0.01	0.01	0.01	0.00	0.00	0.00	0.00	0.01	0.01	0.01	0.01	0.00	0.00	0.01	0.01	0.00	0.00	0.00	0.00
After weighting	0.00	0.00	0.00	0.00	0.00	-0.0	-0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-0.0	0.00	-0.0	-0.0	-0.0	-0.0	-0.0

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



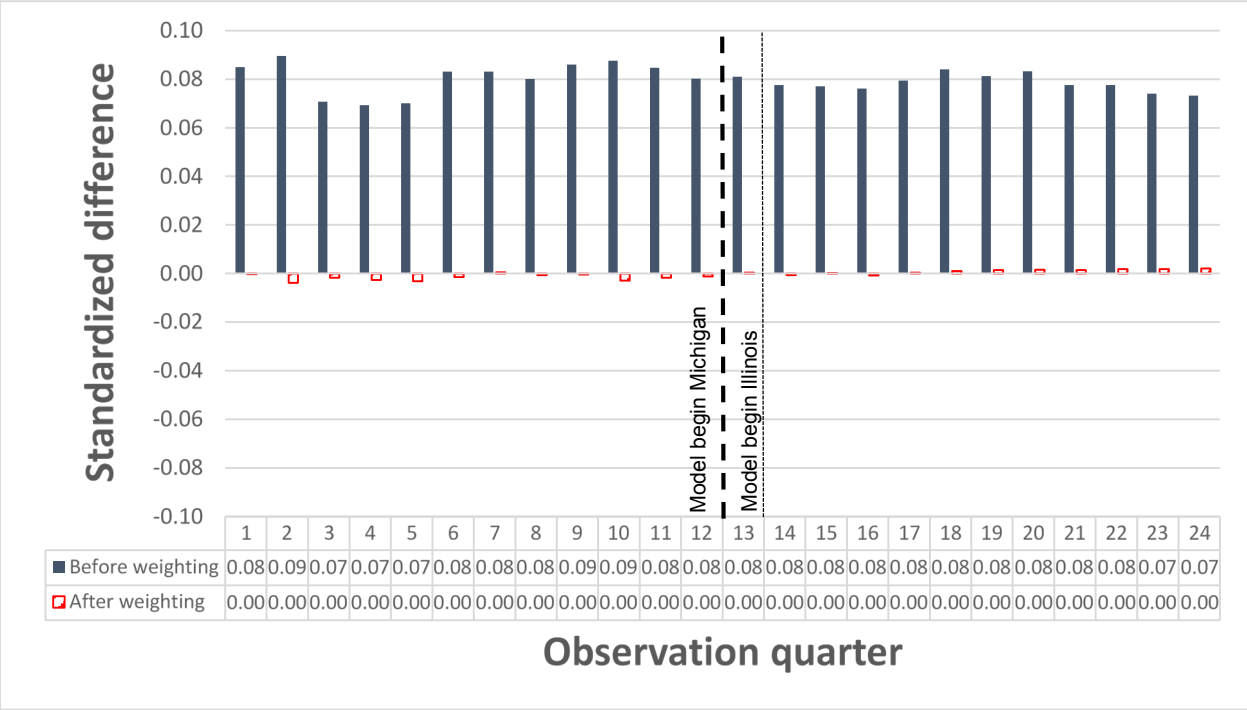
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Before weighting	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
After weighting	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Figure D.4. Beneficiary balance, percentage 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	21	22	23	24
Before weighting	-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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
After weighting	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	0.0	0.0	0.0	0.0

Figure D.5. Beneficiary balance, percentage 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	21	22	23	24
Before weighting	0.08	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	0.08	0.08	0.07	0.07
After weighting	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	0.00	0.00	0.00	0.00	0.00

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

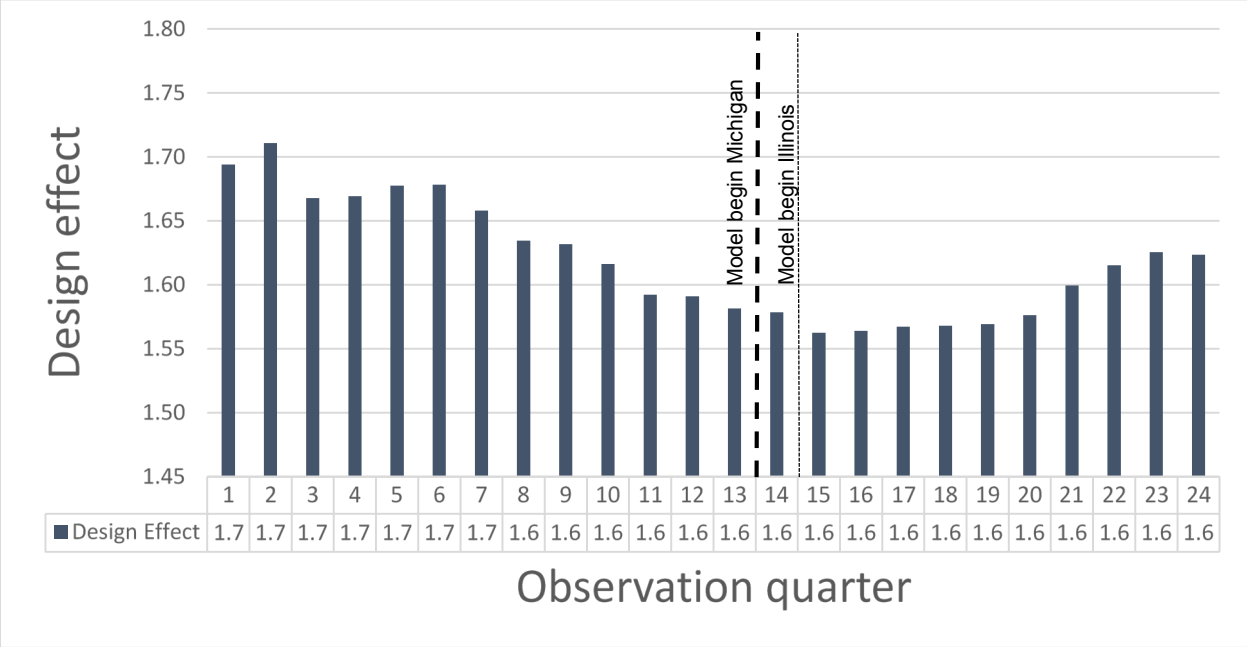
	2012			2013			2014			2015			2016			2017		
	Model	Comparison		Model	Comparison		Model	Comparison		Model	Comparison		Model	Comparison		Model	Comparison	
Characteristic		Before	After		Before	After		Before	After		Before	After		Before	After		Before	After
Rural	13.7	16.4	13.6	13.8	16.6	13.8	13.8	16.7	13.8	13.9	16.5	13.8	13.8	16.6	13.8	14.2	16.9	14.3
Female	41.9	42.1	41.9	42.2	42.6	42.0	42.8	42.8	42.6	42.7	43.0	42.6	43.3	43.6	43.0	43.3	43.4	43.0
Race																		
White	75.5	81.1	75.5	75.9	81.0	76.0	76.2	80.4	76.3	76.5	80.1	76.7	77.1	80.0	77.3	77.5	80.0	77.8
Black	20.0	15.5	20.1	19.5	15.5	19.5	19.0	15.9	19.0	18.3	16.0	18.3	17.6	16.0	17.4	16.9	15.9	16.8
With diabetic ulcers of the lower extremities	80.5	82.7	80.5	80.9	82.7	80.8	80.6	82.5	80.6	80.9	82.5	80.9	82.2	82.8	82.2	82.3	82.4	82.2

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, and the city of Alexandria). Yearly averages were calculated as the unweighted average of the percentage of each characteristic across all quarters in a given year.

C. Choice of adjustment approach: Matching versus 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 match them to treated units, often by 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 or rural and whether beneficiaries had diabetes of the lower extremities, resulted in worse balance on other characteristics or in model state 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 model and comparison samples on the range of characteristics. The full range of available comparison beneficiaries is used as the counterfactual, rather than as a selected subset, so even if a particular comparison beneficiary is not a perfect match to any model state beneficiary, the beneficiary may still improve balance between the full comparison and model groups. This weighting approach was feasible and advantageous because the selection into the model was at the state level, not the person level; therefore, individual-level characteristics played little role in the selection process. 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. Figure D.6 shows the design effects due to weighting.

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



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, 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 ranging from about 1.56 to 1.71 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 did not consider this design effect to be a substantial reduction in the statistical power of our analyses, as shown in Appendices G and H.

APPENDIX E

STATISTICAL PRECISION FOR DETECTING MODEL EFFECTS ON HBO UTILIZATION AND ADVERSE OUTCOMES

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In this appendix, we provide an analysis of the available statistical precision to detect effects of the HBO prior authorization program on different outcomes related to HBO utilization. Statistical precision depends upon 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 precision is the sample size used to generate estimates. All other things being equal, larger sample sizes result in more precise estimates and therefore increased statistical precision. Other factors that affect statistical precision 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 precision: as they increase, statistical precision 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 to balance several measures of beneficiaries in the comparison states with those in the model states.

When using a difference-in-differences analytic approach, statistical precision 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 precision. 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.

E.1 presents 95 percent half-confidence intervals for the various beneficiary-level utilization outcomes. These intervals are based on the observed variance of the difference-in-differences impact estimates, and that variance 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. The confidence interval for outcome J (CI_J) was calculated by using the following formula:

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

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

E.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	Observed effect
Probability of HBO utilization	**622,779**	**620,922**	**0.0784**	**-0.30*** **
Beneficiaries in Illinois	241,590	151,318	0.0980	-0.20***
Beneficiaries in Michigan	191,488	143,909	0.0980	-0.13*
Beneficiaries in New Jersey	189,701	325,695	0.0784	-0.55***
Number of HBO treatments	**622,779**	**620,922**	**0.0392**	**-0.10*** **
Beneficiaries in Illinois	241,590	151,318	0.0392	-0.03
Beneficiaries in Michigan	191,488	143,909	0.0392	-0.04[a]
Beneficiaries in New Jersey	189,701	325,695	0.0392	-0.15***

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

[a]The observed effect is rounded and therefore appears to be larger than the 95% half-confidence interval.

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

E.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	Observed effect
Probability of HBO utilization	**768,007**	**754,949**	**0.0784**	**-0.33*** **
Beneficiaries in Illinois	294,718	185,151	0.0980	-0.18***
Beneficiaries in Michigan	236,118	167,012	0.0980	-0.20***
Beneficiaries in New Jersey	237,171	402,786	0.0784	-0.57***
Number of HBO treatments	**768,007**	**754,949**	**0.0392**	**-0.14*** **
Beneficiaries in Illinois	294,718	185,151	0.0588	-0.06*
Beneficiaries in Michigan	236,118	167,012	0.0588	-0.07**
Beneficiaries in New Jersey	237,171	402,786	0.0392	-0.21***

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

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

E.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	Observed effect
Probability of HBO utilization with physician supervision	**622,779**	**620,922**	**0.0784**	**-0.32*** **
Beneficiaries in Illinois	241,590	151,318	0.0980	-0.23***
Beneficiaries in Michigan	191,488	143,909	0.0980	-0.13*
Beneficiaries in New Jersey	189,701	325,695	0.0784	-0.55***
Proportion of HBO treatments with physician supervision	**6,403**	**5,725**	**0.0392**	**-0.05**
Beneficiaries in Illinois	2,174	1,060	0.0588	-0.04
Beneficiaries in Michigan	2,099	1,325	0.0392	-0.01
Beneficiaries in New Jersey	2,130	3,340	0.0588	-0.15***
Probability of emergency department (ED) visit	**622,779**	**620,922**	**0.3920**	**-0.50***
Beneficiaries in Illinois	241,590	151,318	0.5096	-0.20
Beneficiaries in Michigan	191,488	143,909	0.5488	-0.75**
Beneficiaries in New Jersey	189,701	325,695	0.5292	-0.63*
Number of ED visits	**622,779**	**620,922**	**0.0196**	**-0.01**
Beneficiaries in Illinois	241,590	151,318	0.0196	0.00
Beneficiaries in Michigan	191,488	143,909	0.0196	-0.02[a]
Beneficiaries in New Jersey	189,701	325,695	0.0196	-0.00
Probability of unplanned hospitalization	**622,779**	**620,922**	**0.3332**	**-0.24**
Beneficiaries in Illinois	241,590	151,318	0.4116	-0.10
Beneficiaries in Michigan	191,488	143,909	0.4508	-0.26
Beneficiaries in New Jersey	189,701	325,695	0.4508	-0.39
Number of unplanned hospitalizations	**622,779**	**620,922**	**0.0000**	**0.00**
Beneficiaries in Illinois	241,590	151,318	0.0000	-0.00
Beneficiaries in Michigan	191,488	143,909	0.0000	0.00
Beneficiaries in New Jersey	189,701	325,695	0.0000	-0.00
Probability of death	**622,779**	**620,922**	**0.1568**	**-0.27****
Beneficiaries in Illinois	241,590	151,318	0.2156	-0.15
Beneficiaries in Michigan	191,488	143,909	0.2156	-0.34**
Beneficiaries in New Jersey	189,701	325,695	0.2156	-0.33**

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

[a]The observed effect is rounded and therefore appears to be larger than the 95% half-confidence interval.

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

E.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	Observed effect
Probability of emergency department (ED) visit for lower extremity wound	**622,779**	**620,922**	**0.0196**	**0.03***
Beneficiaries in Illinois	241,590	151,318	0.0392	0.03
Beneficiaries in Michigan	191,488	143,909	0.0392	0.03
Beneficiaries in New Jersey	189,701	325,695	0.0392	0.03
Number of ED visits for lower extremity wound	**622,779**	**620,922**	**0.0000**	**0.00**
Beneficiaries in Illinois	241,590	151,318	0.0000	0.00
Beneficiaries in Michigan	191,488	143,909	0.0000	0.00
Beneficiaries in New Jersey	189,701	325,695	0.0000	0.00
Probability of unplanned hospitalization for lower extremity wound	**622,779**	**620,922**	**0.0392**	**-0.01**
Beneficiaries in Illinois	241,590	151,318	0.0392	-0.00
Beneficiaries in Michigan	191,488	143,909	0.0588	-0.02
Beneficiaries in New Jersey	189,701	325,695	0.0392	-0.03
Number of unplanned hospitalizations for lower extremity wound	**622,779**	**620,922**	**0.0000**	**-0.00**
Beneficiaries in Illinois	241,590	151,318	0.0000	-0.00
Beneficiaries in Michigan	191,488	143,909	0.0000	-0.00
Beneficiaries in New Jersey	189,701	325,695	0.0000	-0.00
Probability of amputation	**622,779**	**620,922**	**0.0980**	**0.02**
Beneficiaries in Illinois	241,590	151,318	0.1176	-0.04
Beneficiaries in Michigan	191,488	143,909	0.1372	0.17*
Beneficiaries in New Jersey	189,701	325,695	0.1372	-0.06

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

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

E.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	Observed effect
Probability of HBO utilization with physician supervision	**768,007**	**754,949**	**0.0784**	**-0.35*** **
Beneficiaries in Illinois	294,718	185,151	0.0980	-0.20***
Beneficiaries in Michigan	236,118	167,012	0.0980	-0.20***
Beneficiaries in New Jersey	237,171	402,786	0.0784	-0.60***
Proportion of HBO treatments with physician supervision	**8,694**	**7,882**	**0.0392**	**-0.04[a]**
Beneficiaries in Illinois	3,116	1,527	0.0392	-0.02
Beneficiaries in Michigan	2,811	1,767	0.0392	-0.01
Beneficiaries in New Jersey	2,767	4,588	0.0588	-0.12***
Probability of emergency department (ED) visit	**768,007**	**754,949**	**0.3528**	**-0.58****
Beneficiaries in Illinois	294,718	185,151	0.4508	-0.34
Beneficiaries in Michigan	236,118	167,012	0.4900	-0.86***
Beneficiaries in New Jersey	237,171	402,786	0.4900	-0.62*
Number of ED visits	**768,007**	**754,949**	**0.0196**	**-0.01**
Beneficiaries in Illinois	294,718	185,151	0.0196	-0.00
Beneficiaries in Michigan	236,118	167,012	0.0196	-0.01
Beneficiaries in New Jersey	237,171	402,786	0.0196	-0.00
Probability of unplanned hospitalization	**768,007**	**754,949**	**0.2940**	**-0.33***
Beneficiaries in Illinois	294,718	185,151	0.3724	-0.15
Beneficiaries in Michigan	236,118	167,012	0.4116	-0.43*
Beneficiaries in New Jersey	237,171	402,786	0.3920	-0.46*
Number of unplanned hospitalizations	**768,007**	**754,949**	**0.0000**	**-0.00**
Beneficiaries in Illinois	294,718	185,151	0.0000	-0.00
Beneficiaries in Michigan	236,118	167,012	0.0000	0.00
Beneficiaries in New Jersey	237,171	402,786	0.0000	-0.00
Probability of death	**768,007**	**754,949**	**0.1372**	**-0.16***
Beneficiaries in Illinois	294,718	185,151	0.1764	-0.03
Beneficiaries in Michigan	236,118	167,012	0.1960	-0.25*
Beneficiaries in New Jersey	237,171	402,786	0.1960	-0.22*

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

[a]The observed effect is rounded and therefore appears to be larger than the 95% half-confidence interval.

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

E.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	Observed effect
Beneficiaries with diabetic lower extremity wounds				
Number of denied HBO claims				
Q1	38,673	38,591	0.0784	0.15***
Q2	41,471	40,796	0.0588	0.10**
Q3	44,036	42,827	0.0392	-0.02
Q4	45,005	43,681	0.0392	-0.01
Q5	45,691	44,069	0.0392	-0.03
Q6	45,775	43,971	0.0392	-0.03
Proportion of HBO claims denied				
Q1	340	317	0.0392	0.03*
Q2	240	281	0.0588	0.01
Q3	233	265	0.0392	-0.01
Q4	245	268	0.0392	-0.01
Q5	183	214	0.0392	-0.01
Q6	152	212	0.0392	-0.01*
Beneficiaries with any included condition				
Number of denied HBO claims				
Q1	47,305	46,558	0.0784	0.18***
Q2	50,543	49,325	0.0784	0.11**
Q3	53,788	51,919	0.0392	-0.01
Q4	55,091	53,222	0.0392	-0.02
Q5	56,192	53,982	0.0392	-0.04*
Q6	56,529	54,177	0.0392	-0.03
Proportion of HBO claims denied				
Q1	415	388	0.0392	0.06**
Q2	339	370	0.0392	0.02*
Q3	335	380	0.0392	-0.01
Q4	355	385	0.0392	-0.01
Q5	273	341	0.0392	-0.01
Q6	253	349	0.0392	-0.01*

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

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

In general, our analyses of outcomes related to HBO utilization had high statistical precision. Although not presented here, the analysis of most outcomes also had high statistical power, which accounts for both Type I and Type II errors. For example, the minimum detectable effect for the probability of any HBO utilization, which takes into account Type I and Type II errors, was +/-0.11, much smaller than the observed effect of -0.32. 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.

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APPENDIX F

STATISTICAL PRECISION TO DETECT THE EFFECTS OF THE MODEL ON COSTS

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F.1 presents precision estimates for the expenditure outcomes, with separate results for beneficiaries with diabetic lower extremity wounds and beneficiaries with any included condition. See Appendix E for more information on how precision estimates were calculated.

F.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	Observed effect[a]
Beneficiaries with diabetic lower extremity wounds				
HBO expenditures	**622,779**	**620,922**	**20.2268**	**-58.95*****
Beneficiaries in Illinois	241,590	151,318	21.7164	-14.19
Beneficiaries in Michigan	191,488	143,909	24.8523	-43.86***
Beneficiaries in New Jersey	189,701	325,695	24.3036	-130.19***
Total Medicare FFS expenditures	**622,779**	**620,922**	**360.9274**	**215.66**
Beneficiaries in Illinois	241,590	151,318	386.4657	498.11*
Beneficiaries in Michigan	191,488	143,909	392.4436	-98.40
Beneficiaries in New Jersey	189,701	325,695	410.7889	206.18
Beneficiaries with any included condition				
HBO expenditures	**768,007**	**754,949**	**19.2468**	**-55.74*****
Beneficiaries in Illinois	294,718	185,151	20.7364	-14.38
Beneficiaries in Michigan	236,118	167,012	23.3236	-46.36***
Beneficiaries in New Jersey	237,171	402,786	22.6180	-115.28***
Total Medicare FFS expenditures	**768,007**	**754,949**	**324.2956**	**193.95**
Beneficiaries in Illinois	294,718	185,151	347.3056	429.50*
Beneficiaries in Michigan	236,118	167,012	353.0679	-123.30
Beneficiaries in New Jersey	237,171	402,786	365.6509	248.87

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

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

As with the utilization estimates, we generally measured the impact estimates for cost outcomes with high precision—although, all outcomes had statistical power that was less than 80 percent.

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APPENDIX G

Qualitative Analysis

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

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

Domain 1. Utilization and expenditures

Overall model effectiveness in reducing medically unnecessary HBO use

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

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

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

Domain 2. Quality of care

Delayed access to care

HBO providers' main concern following implementation of the prior authorization model for HBO is that, in their experience, access to HBO treatment is delayed for some beneficiaries due to what they perceive as stringent review of pre-existing documentation requirements enforced under the model. These comments were consistent across all three model states. As one HBO provider explained, for their facility, the number of beneficiaries who were non-affirmed for HBO therapy because they are deemed medically ineligible was perceived to be small. However, they noted that the number of beneficiaries whose PARs were non-affirmed initially and then affirmed later was growing. Other HBO facility staff agreed with this perception, and noted that while they generally support implementation of the prior authorization model, they believe some patients may experience delayed care.

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

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

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

HBO providers report that PARs for beneficiaries who experience a delay in care are typically non-affirmed pending submission of additional tests and medical records, or clarification of previously submitted documentation. In cases in which a beneficiary's PAR is later affirmed after initially being non-affirmed due to missing or incomplete documentation, providers note that they typically do not start treatment until authorization occurs and the resulting delay in providing HBO therapy may have a negative impact on the patient's condition. Some instances of delay reflect a learning curve experienced by HBO providers, as they become

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

familiar with the documentation required to establish medical necessity for the five conditions covered under the model. Some HBO providers noted that they became more proficient with the PAR submission process over time and had their affirmation rate increase, leading to patients experiencing fewer delays as a result.

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

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

Ineligible conditions

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

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

- Diabetic patients with wounds for which it is difficult to show that adequate debridement has been done.

Some HBO providers also indicate that in cases where alternatives to HBO therapy are available or the patient does not meet medical necessity requirements for HBO therapy prior authorization, HBO may be perceived by these providers as the *preferable* course of treatment because it promotes faster, longer lasting healing, is less intrusive than other treatments, and may reduce the risk of later infection. According to one HBO provider interviewed:

Beneficiary experiences

The beneficiaries and caregivers we interviewed typically report being referred to HBO by other practitioners, including dentists, primary care physicians, oncologists, and podiatrists. Following referral, their experiences varied. Some beneficiaries reported waiting just a day from the submission of the PAR by their provider to the scheduling of their HBO sessions, while others were still waiting for an affirmation at the time of their interview, several months after the initial PAR submission. Several beneficiaries questioned the economic benefit of prior authorization, reasoning that the costs associated with wound care, amputations, and physical therapy seemed comparable to that of HBO, for what they perceived to be less effective care and to result in less desirable outcomes.[9]

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

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

Few beneficiaries reported adverse health impacts while waiting for prior authorization for HBO treatment. Some reported visits to other providers to treat their condition while they waited for their PAR decision and mentioned their concerns about the out of pocket expenses they incurred for these visits. Several beneficiaries also noted that they feared amputation, infection,

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

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

Among the 32 facilities that responded to the online survey, 56.3 percent of HBO facilities noted that prior authorization has resulted in some beneficiaries who are not affirmed for HBO relying on emergency care to treat their condition, while 81.3 percent perceived that some beneficiaries are experiencing adverse health outcomes as a result of not being affirmed for HBO therapy.

Domain 4. Model operations

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

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

Prior authorization implementation

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

Education and training

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

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

MACs further report hosting webinars for HBO providers and posting information about the model received from CMS to their websites. In addition to these formal resources, MAC staff noted in interviews that they give individual support to HBO providers as needed. Open communication with providers was a common theme among interviewees. According to one MAC staff member, if a reviewer notices a trend in errors or missing information on PARs, that reviewer will reach out to the HBO provider to engage in a discussion and help the provider identify the issues causing the errors. Further, if a provider disagrees with a decision and would like to discuss it with a MAC physician, MAC staff noted that they allow the provider to speak to a medical director at the MAC to review the interpretation of guidelines.

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

Processing reviews and decisions

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

timeframe. For example, one staff member noted they achieve an average turnaround time of about five business days.

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

Medical necessity guidelines

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

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

CMS CPI Perspectives

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

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

According to interviewees, HBO model challenges included the effects of having NCD and LCD differences across states, which led to lower rates of approval in New Jersey where a LCD was used. Interviewees discussed the need for MACs to present to providers all of the reasons for non-affirmation of a prior authorization request at the onset of submission, in an effort to reduce resubmissions and confusion among providers. In addition, the interviewees believed that providers often requested more specific information and definitions from CMS and the MACs, reflecting the need for providers and all stakeholders to receive more communication, outreach, and education. They noted that the lack of specific non-affirmation codes that clarify why a PAR was not affirmed also resulted in provider concern and confusion, and these specific codes would have been beneficial.

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

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