TO: Novo Nordisk

FROM: Avalere Health

DATE: February 2019

RE: Estimated Federal Budget Impact of H.R.1953 – Treat and Reduce Obesity Act of 2017

SUMMARY

Avalere Health was asked to estimate the cost or savings to the federal government associated with the H.R. 1953 – Treat and Reduce Obesity Act of 2017. The proposed legislation would allow Medicare Part D coverage of drugs for the treatment of obesity and expand the types of health care providers qualified to furnish intensive behavioral therapy (IBT) as a form of obesity treatment to Medicare beneficiaries.

Avalere estimates that the proposed Medicare coverage changes would decrease federal government spending by approximately $25M over the fiscal year (FY) 2020-2029 budget window. Our estimate reflects the increase in cost to the federal government from coverage of, and payment for, drugs for the treatment of obesity in Medicare Part D, as well as increased utilization of IBT among Medicare beneficiaries. Our estimate also assumes a certain level of weight loss resulting from obesity treatments and corresponding federal savings due to lower Medicare spending for impacted beneficiaries.

Estimated Change in Federal Spending Due to H.R. 1953 – Treat and Reduce Obesity Act of 2017

Outlays, by Fiscal Year, in Millions of Dollars

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2020-2024	2020-2029
Total Change in Federal Spending	-$6.0	-$7.3	-$6.0	-$4.5	-$2.7	-$1.6	-$0.8	$0.2	$1.3	$2.6	**-$26.4**	**-$24.8**

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Source: Avalere analysis of H.R. 1953

BACKGROUND

Currently, drugs for the treatment of obesity are excluded from coverage under the Medicare Part D program. The Medicare Prescription Drug Manual, in Chapter 6, 20.1 – Excluded Categories, lists "Agents when used for anorexia, weight loss, or weight gain (even if used for a noncosmetic purpose (i.e., morbid obesity))" in the compilation of drugs excluded from Medicare Part D coverage.[1] The lifting of the exclusion would lead to the United States Pharmacopeia (USP) Medicare Model Guidelines to include the anti-obesity agents class from their USP Drug Classification System in the model guidelines to ensure coverage of a least two anti-obesity agents by each Medicare Part D plan. USP classifies 9 brand products and 7 generic formulations as anti-obesity agents.

Medicare covers and pays for IBT for obesity as a preventive service via either individual or group sessions.[2] Medicare will pay for up to 22 visits for IBT in a 12-month period. At the 6-month visit, a beneficiary is evaluated for the amount of weight loss. To be eligible for additional visits for months 7 through 12, the beneficiary must have lost at least 3 kg (6.6 lbs), which corresponds to 1 Body Mass Index (BMI) point, during the first 6 months.

Currently, only primary care physicians and a limited number of other provider types are allowed to bill Medicare for IBT.[3] The proposed legislation would allow any other physician specialties, clinical psychologists, registered dietitians or nutrition professionals as well as an evidence-based, community-based lifestyle counseling program approved by the Secretary to offer IBT for Medicare beneficiaries. Increasing coverage of IBT is expected to expand the pool of providers offering those services and lead to increased utilization of IBT by Medicare beneficiaries with obesity.

[1] Medicare Prescription Drug Benefit Manual. Chapter 6 - Part D Drugs and Formulary Requirements.20.1 – Excluded Categories. https://www.cms.gov/Medicare/Prescription-Drug Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf.

[2] CPT codes G0447 (individual 15-minute session) or G0473 (Group 30-minute session) need to be accompanied by one of the ICD-10 diagnosis codes: Z68.30, Z68.31, Z68.32, Z68.33, Z68.34, Z68.35, Z68.36, Z68.37, Z68.38, Z68.39, Z68.41, Z68.42, Z68.43, Z68.44, or Z68.45. https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html#OBESITY_IBT

[3] General Practice, Family Practice, Internal Medicine, Obstetrics/Gynecology, Pediatric Medicine, Geriatric Medicine, Nurse Practitioner, Certified Clinical Nurse Specialist, Physician Assistant. https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?&NcaName=Intensive%20Behavioral%20Therapy%20for%20Obesity&NCAId=253

DATA SOURCES

Avalere used the following data sources to develop the scoring estimate:

- The Centers for Medicare & Medicaid Services (CMS)' 5% Standard Analytic File (SAF): Carrier and Hospital Outpatient Department, 2017[4]
- Agency for Healthcare Research and Quality (AHRQ) Medical Expenditure Panel Survey (MEPS), 2016[5]
- CMS' Medicare Current Beneficiary Survey (MCBS), 2015[6]
- Part D population growth and per capita Medicare spending, 2018 Medicare Trustees Report and Tables[7]
- Consumer price index for urban consumers (CPI-U) for prescription drugs, U.S. city average, unadjusted, Bureau of Labor Statistics (BLS), 2013-2017[8]
- CPI-U projections, Congressional Budget Office (CBO), Medicare Baseline, April 2018[9]
- CMS' Decision Memo for Intensive Behavioral Therapy for Obesity (CAG-00423N)[10]
- CBO. Estimating the Effects of Federal Policies Targeting Obesity: Challenges and Research Needs. October 26, 2015[11]
- Montesi, Luca et al. "Long-term weight loss maintenance for obesity: a multidisciplinary approach" Diabetes, metabolic syndrome and obesity: targets and therapy vol. 9 37-46. 26 Feb. 2016
- Persistence of newer anti-obesity medications in a real-world setting. Ganguly, Rahul et al. Diabetes Research and Clinical Practice , Volume 143 , 348 – 356.
- Cawley J, Meyerhoefer C, Biener A, Hammer M, Wintfeld N. Savings in Medical Expenditures Associated with Reductions in Body Mass Index Among US Adults with Obesity, by Diabetes Status. *Pharmacoeconomics*. 2014;33(7):707-22.

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[4] Center for Medicare & Medicaid Services, Standard Analytic Files, accessed at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/StandardAnalyticalFiles.html
[5] AHRQ. Medical Expenditure Panel Survey. https://meps.ahrq.gov/mepsweb/
[6] CMS. Medicare Current Beneficiary Survey. https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS/index.htmllllllll6
[7] CMS. 2018 Medicare Trustees Report, accessed at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf
[8] Bureau of Labor Statistics, Consumer Price Index, accessed at: https://www.bls.gov/cpi/tables/detailed-reports/home.htm
[9] CBO. Medicare Baseline. April 2018. https://cbo.gov/sites/default/files/recurringdata/51302-2018-04-medicare.pdf
[10] https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?&NcaName=Intensive%20Behavioral%20Therapy%20for%20Obesity&NCAId=253
[11] CBO. Estimating the Effects of Federal Policies Targeting Obesity: Challenges and Research Needs. October 2015. https://www.cbo.gov/publication/50877

- Wenqing Su, Fang Chen, Timothy M. Dall, Tracy Zvenyach, Theodore K. Kyle & Leigh Perreault (2018) Where can obesity management policy make the largest impact? Evaluating sub-populations through a microsimulation approach, Journal of Medical Economics, 21:9, 936-943

ASSUMPTIONS AND METHODOLOGY

- **Increase in IBT Utilization Due to Provider Expansion:** Avalere used 5% SAF to estimate approximately 5,100 IBT users in the sample, which extrapolated to the whole fee-for-service (FFS) Medicare population yields a little over 100,000 beneficiaries. Separately, Avalere determined a number of Medicare beneficiaries in the 5% sample diagnosed with obesity based on the appropriate diagnosis code included on the physician office or hospital outpatient claim. Extrapolation to the whole FFS population yields an estimate of approximately 4 million beneficiaries diagnosed with obesity. Therefore, approximately 3% of FFS beneficiaries diagnosed with obesity were receiving IBT in 2017. The actual level of Medicare beneficiaries with obesity, defined as BMI>=30, is much higher. The MEPS-reported BMI distribution among Medicare beneficiaries indicates 32% fall within BMI levels indicating obesity.

  However, Avalere assumed that beneficiaries with medical diagnosis of obesity are more likely to benefit from expanded access to IBT due to more provider types allowed to offer this service as per proposed legislation. Specifically, we assumed double the rate of IBT use among Medicare beneficiaries diagnosed with obesity, 6% compared to the current 3%. Avalere then estimated the total number of IBT users through 2029 using Part B FFS enrollment projections from the 2018 Medicare Trustees report.

- **Increase in Anti-Obesity Agents Utilization Due to Part D Coverage:** Avalere used MCBS data to estimate ~37,000 Medicare beneficiaries were using anti-obesity agents in 2015 even though not covered under Part D. We used that estimate as a baseline for calculating the uptake in utilization once anti-obesity agents are covered under Part D. Specifically, Avalere applied demand elasticity assumption of 0.15 where every 1% decrease in out-of-pocket spending is associated with 0.15% increase in utilization. Therefore, we assumed that as opposed to the current full patient liability associated with anti-obesity treatments, under Part D coverage beneficiaries will pay only 25% cost-sharing based on the a 26-week treatment cost (assuming standard benefit design and initial coverage limit when prescriptions for anti-obesity agents are filled). This reduction in beneficiary OOP cost translates to 11% increase in utilization i.e. the number of beneficiaries that will start using anti-obesity agents once covered by Part D. Avalere estimated the year-over-year growth in anti-obesity agents' users through 2029 using Part D enrollment projections from the 2018 Medicare Trustees report.

- **Treatment Completion Rates, Weight Loss Level, and Maintenance:** Several studies indicate that a healthy weight loss of 5%–10% can be achieved through both behavioral and pharmacological treatments, but weight is gradually regained in a large percentage

of individuals.[12] For the purposes of this analysis, we assumed that everyone who completes a full course of treatment will see a 5% drop in weight which corresponds to 5% drop in BMI. Based on literature findings, we further assumed 50% of beneficiaries who achieve initial 5% weight loss will return to their original weight within 5 years and another 25% will return to their original weight within 10 years. In other words, only 25% of beneficiaries will be able to keep their weight off throughout the 10-year analysis period.

For IBT, Avalere determined what portion of the new users will complete the full course of treatment and achieve at least 5% weight loss that corresponds to the drop of 2 BMI points. Our assumption was based on Medicare-claims based finding of 5% of IBT users having more than 6 visits in a year, which would indicate that they must have dropped at least 3kg/6.6 lbs (1 BMI point) in order to continue IBT. Given that some beneficiaries lose more than the required minimum weight level, we used the 5% assumption to identify a share of IBT users that would lose 6kg/13.2lbs (2 BMI points). We further assumed that all remaining new IBT users will not complete treatment and achieve weight loss.

For anti-obesity drugs, Avalere determined that approximately 25% of new users will complete the full course of treatment defined as adherence throughout 26 weeks (6 months) from therapy initiation. Research found that as many as three-quarters of all patients initiating therapy with an anti-obesity medication were classified as non-persistent within the first 6 months of follow-up.[13]

- **Medicare Spending for IBT:** Avalere used the 5% SAF to estimate Medicare payment for IBT in the physician office. In 2017, the average Medicare payment per visit was $25. We assumed that Medicare reimbursement rate would grow at the same rate as CPI-U factors used by CBO for payment updates through 2028, on average 2.4% annually. We assumed a full course of IBT treatment to achieve at least 3kg/6.6 lbs weight loss will consist of 14 visits/sessions within 6 months given the Medicare coverage pattern of one visit every week for the first month and one visit every other week for the following months.[14] We assumed a partial treatment to consist of 2 visits, which is the current average number of IBT visits per beneficiary identified in Medicare claims data. Finally, Avalere calculated the additional costs to Medicare from providing IBT for obesity using the assumptions of the treatment complication rates among new users.

- **Medicare Spending for Anti-Obesity Agent Treatment:** Avalere used GoodRx pharmacy drug price aggregator to estimate average cost per tablet among 21 drugs classified as anti-obesity agents by USP. We then calculated total cost associated with

[12] Montesi, Luca et al. “Long-term weight loss maintenance for obesity: a multidisciplinary approach” Diabetes, metabolic syndrome and obesity: targets and therapy vol. 9 37-46. 26 Feb. 2016

[13] Persistence of newer anti-obesity medications in a real-world setting. Ganguly, Rahul et al. Diabetes Research and Clinical Practice , Volume 143 , 348 – 356.

[14] https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?&NcaName=Intensive%20Behavioral%20Therapy%20for%20Obesity&NCAId=253

26-week full treatment (182 tablets) at ~$442 and 8-week partial treatment[15] (56 tablets) at ~$136. We assumed that anti-obesity agents' cost would grow based on a 5-year average of the CPI-U for prescription drugs from 2013-2017, which was 3.4%. Finally, Avalere calculated the additional costs to Medicare from providing IBT for obesity using the assumptions of the treatment complication rates among new users.

- **Medicare Savings Due to Lower Rates of Obesity:** In order to estimate the initial, specific BMI levels among beneficiaries who would use IBT or anti-obesity agents under the proposed policy, Avalere assumed the BMI distribution among overall Medicare population with obesity. Specifically, as per MEPS data, 10% of Medicare beneficiaries with obesity have BMI of 30, 16% has BMI of 31, etc. Overall, 58% of Medicare beneficiaries with obesity have BMI between 30 and 34, another 25% have BMI between 35 and 39, 10% have BMI between 40 and 44 and 6% have BM I>=45. Avalere used this distribution to calculate reductions in BMI levels due to 5% weight loss. We then compared the healthcare costs, reflective of total annual spending across all settings of care, including drugs for Medicare beneficiaries associated with any given BMI level to estimate potential savings associated with decrease in BMI for people who complete their anti-obesity treatments and achieve and maintain weight loss. Finally, Avalere grew the amount of savings per person by projected Medicare program spending in the 2018 Medicare Trustees report.

- **Medicare Financing Adjustments:** After estimating the Medicare spending impact associated with increased availability of IBT providers and coverage of anti-obesity agents, we adjusted the spending to reflect the Medicare Advantage (MA) beneficiaries. We increased the estimated, additional Medicare FFS payments and savings associated with increase in utilization of IBT and anti-obesity agents based on the CBO's assumptions about overall MA costs as a percentage of FFS costs, projected forward. We calculated the federal share of FFS spending by removing the impact of beneficiary copays and Part B premiums. We also accounted for the federal savings associated with state Medicaid payment of dual-eligible beneficiaries' Part B copays and premiums. Finally, since our estimates were based on the calendar year data, we adjusted annual amounts to reflect fiscal years to align with the federal government budgeting window. For example, for FY2020, we used 25 percent of the 2019 estimate to reflect the last quarter of 2019 and 75 percent of the 2020 estimate to reflect the first three quarters of 2020.

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[15] The mean duration of persistence for all AOMs ranged around 7-8 weeks. Persistence of newer anti-obesity medications in a real-world setting. Ganguly, Rahul et al. Diabetes Research and Clinical Practice , Volume 143 , 348 – 356.