



March 1, 2018

Centers for Medicare & Medicaid Services
Submitted via: www.regulations.gov
7500 Security Blvd
Baltimore, MD 21244

Re: Comments on Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Call Letter

Dear Ms. Seema Verma,

Novo Nordisk Inc. ("Novo Nordisk") appreciates the opportunity to comment on the 2019 Advance Notice and draft Call Letter (the draft Call Letter). Headquartered in Denmark, and with almost 5,000 U.S. employees, Novo Nordisk is a global health care company with 90 years of innovation and leadership in diabetes, obesity, hemophilia and growth hormone disorders. Novo Nordisk is committed to the goal of ensuring patients have access to high-quality, affordable health care, and to improving patient protections in health insurance coverage.

Novo Nordisk applauds CMS' efforts to promote and enhance the quality of health plan offerings in both the MA and Part D programs. Our comment letter addresses the following points:

- Novo Nordisk supports the adoption of a new measure for 2019 Star Ratings, "Statin Use in Persons with Diabetes," but encourages additional emphasis on the link between cardiovascular disease and diabetes through future measure development.
- Novo Nordisk supports CMS' proposal to delay the summer formulary update window from July to late summer to allow plan sponsors to include newly approved drugs in 2019 bids. Novo Nordisk also supports the proposal to add two new enhancement-only windows in fall 2018 and January 2019 that will feed into the Medicare Plan Finder and ensure beneficiaries have the most current information.

Novo Nordisk addresses these comments in more detail below.

Section I – Parts C and D:

Enhancements to the 2019 Star Ratings and Future Measurement Concepts - New Measures for 2019 Star Ratings

Statin Use in Persons with Diabetes (SUPD) (Part D)

Novo Nordisk applauds CMS for the adoption of a Star Ratings Measure for 2019 to support statin use in persons living with diabetes. Statin use in patients living with diabetes is an evidence-based standard of care. The adoption of this Star Ratings measure will align with both the United States Preventive Service Task Force (USPSTF) and American Diabetes Association (ADA) standards of medical care in diabetes. Patients with Type 2 diabetes have an increased prevalence of lipid abnormalities, contributing to their high risk of cardiovascular disease (CVD).¹ Multiple clinical trials have demonstrated the beneficial effects of statin therapy on cardiovascular outcomes in subjects with and without coronary heart disease.² The USPSTF recommends that adults without a history of CVD (i.e., symptomatic coronary artery disease or ischemic stroke) use a low-to moderate-dose statin for the prevention of CVD events and mortality when all of the following criteria are met: 1) they are ages 40 to 75 years; 2) they have 1 or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking); and 3) they have a calculated 10-year risk of a cardiovascular event of 10% or greater.³ The USPSTF has rated statin use in patients with diabetes with “B” grade.⁴ This grade denotes that the USPSTF recommends the service and there is high certainty that the net benefit is moderate.⁵ The ADA recommends statin use of varying levels of intensity in all patients with diabetes (barring medical conditions resulting in a contraindication of statin use), recognizing that CVD is a dangerous co-morbidity of diabetes that must be appropriately treated.⁶

Novo Nordisk applauds CMS for updating the 2019 Star Ratings to include this measure on statin use as the measure aligns with evidence-based care and is in tune with the medical community’s views on diabetes care. However, we encourage CMS to consider funding additional measure development that focuses more specifically on the link between CVD and diabetes. The risk of developing cardiovascular disease is four times greater in people living with type 2 diabetes as compared to those without diabetes.⁷ About 70% of deaths in people with type 2 diabetes are caused by cardiovascular disease, making it the leading cause of death in people with type 2 diabetes.⁸ Specifically, we encourage CMS to promote the development and implementation of a diabetes & CVD composite measure that focuses on overlapping treatment processes and goals. Such a measure could focus on aspects of health care such as blood pressure screening and control, lipid screening and control, and tobacco cessation.

¹ http://care.diabetesjournals.org/content/diacare/suppl/2017/12/08/41.Supplement_1.DC1/DC_41_S1_Combined.pdf

² http://care.diabetesjournals.org/content/diacare/suppl/2017/12/08/41.Supplement_1.DC1/DC_41_S1_Combined.pdf

³ <https://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/>

⁴ <https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions>

⁵ <https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions>

⁶ http://care.diabetesjournals.org/content/diacare/suppl/2017/12/08/41.Supplement_1.DC1/DC_41_S1_Combined.pdf

⁷ <https://www.heartoftype2.com/know-your-risk.html>

⁸ <https://www.heartoftype2.com/know-your-risk.html>

Section III – Part D, Formulary Submissions
CY 2019 Formulary Submission Window

Novo Nordisk supports CMS' decision to delay the summer formulary update window and to add a Medicare Plan Finder update window in the fall and a formulary update window in January of the coverage year. These important update opportunities will allow for improved beneficiary transparency, which will help ensure beneficiaries can make informed enrollment decisions based on the most up-to-date information and that their chosen plan best meets their coverage and affordability needs.

Novo Nordisk appreciates this opportunity to offer our suggestions on the 2019 Advance Notice and Draft Call Letter. If you have any questions or need any further information relating to our comments, please do not hesitate to contact Tricia Brooks at TIIB@novonordisk.com or +1 202-626-4528

Sincerely,

A handwritten signature in dark ink, appearing to read 'Tricia Brooks', with a long horizontal stroke extending to the right.

Tricia Brooks
Vice President, Public Affairs
Novo Nordisk Inc.