PRODUCE PRESCRIPTIONS as a Novel Supplemental Benefit in Medicare Advantage

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Innovating to address the social determinants of health

Introduction

Food insecurity, broadly defined as a "household-level economic and social condition of limited or uncertain access to adequate food," affects over fifty million Americans nationwide.[1],[2] It is an issue of both availability and quality—hunger alone accounts for only part of the picture. Imbalanced diets drive a host of chronic illnesses, including Type 2 diabetes, coronary artery disease, chronic kidney disease, hypertension, and obesity, to name a few.[3]

Nutrition-based interventions offer a critical set of tools to combat these conditions. The benefits of medically tailored meals have already been well-documented in the medical literature; a growing body of evidence suggests the same for produce prescriptions.[4,5,6]

Produce Prescriptions

A Produce Prescription Program is a health intervention for patients who are eligible due to health risk or diet-related diagnosis, lack access to nutritious foods, and are referred by a health care provider or health insurance plan. These prescriptions are fulfilled through food retail and enable patients to access produce with no added fats, sugars, or salt, at low or no cost to the patient. When appropriately dosed, Produce Prescription Programs are designed to improve healthcare outcomes, optimize medical spend, and increase patient engagement and satisfaction. (National Produce Prescription Collaborative, February 2020.)

Produce prescriptions target food insecurity in two key ways: they lower financial barriers to food access and simultaneously encourage consumption of fresh produce.[7,8] Studies have revealed their efficacy. In addition to addressing household food insecurity, produce prescriptions have led to clinically significant reductions in indicators such as hemoglobin A1c and blood pressure.[9,10,11] Their broader effects are manifold. Produce prescriptions reinforce health educational initiatives, bolster patient-provider relationships, and stimulate local business.[12,13]

A number of new opportunities have emerged to cover produce prescriptions within the Medicare Advantage program. Medicare Advantage—also known as Medicare Part C—uses private-sector insurance plans to administer standard Medicare health care benefits (i.e., benefits under Medicare Parts A and B). Medicare Advantage plans may also administer additional benefits not covered by Medicare Parts A or B; these are known as supplemental benefits. This issue brief provides an analysis of whether and how Medicare Advantage plans may cover produce prescriptions within three categories of supplemental benefits: general supplemental benefits, Special Supplemental Benefits for the Chronically Ill (SSBCI), and supplemental benefits within the Value-Based Insurance Design (VBID) program.

General Supplemental Benefits

The Centers for Medicare and Medicaid Services (CMS or "the Agency") has established four requirements for supplemental benefits. They must:

(1) extend to services not covered under Medicare Parts A or B,

(2) be "primarily health related,"

(3) incur a non-zero direct medical cost to the plan in question, and

(4) apply uniformly to all plan beneficiaries.[14]

Although produce prescriptions may plausibly appear to meet these criteria, CMS does not generally

consider nutritional interventions an appropriate general supplemental benefit*. The challenge involves the requirement for benefits to be "primarily health related." In a recent guidance document, CMS lists several food-related programs, including "meals beyond [a] limited basis" and "food and produce to assist. . .in meeting nutritional needs," as examples of *non*-primarily health related supplemental benefits.[15] As long as CMS applies this interpretation to general Medicare Advantage supplemental benefits, general supplemental benefits is likely not the appropriate pathway for **most nutritional interventions.**

Food as General Supplemental Benefits

CMS recognizes some limited exceptions to its general position that nutritional interventions may not be covered as general supplemental benefits.[16] Meals (as opposed to "food" more generally) may be offered (1) "immediately following surgery, or an inpatient hospital stay, for temporary duration, typically a four-week period, per enrollee per year" after which "providers should refer enrollee to community and social services for further meals, if needed." [17] Also permissible are (2) meals that are "for a chronic condition for a temporary period, typically two weeks, per enrollee per year, and are part of a supervised program designed to transition the enrollee to lifestyle modifications." [18]

SSBCI

The Bipartisan Budget Act of 2018 significantly expanded the range of supplemental benefits that Medicare Advantage plans may offer by creating a new category of supplemental benefits: Special Supplemental Benefits for the Chronically Ill or "SSBCI." In creating this new category, Congress waived both the "primarily health related" and uniformity requirements described above, allowing plans to use SSBCI to deliver a range of novel services—including produce prescriptions—to enrollees living with chronic illness.

- **Definition of Chronic Illness:** The Bipartisan Budget Act defines chronic illness as a condition which "(1) is life threatening or significantly limits the overall health or function of the enrollee, (2) has a high risk of hospitalization or other adverse health outcomes, and (3) requires intensive care coordination."[19] This is further clarified through regulation and in guidance documents, in which CMS provides a non-exhaustive list of conditions which it deems rise to the level of "chronic illness." Eligible conditions are coronary artery disease, peripheral vascular disease, diabetes mellitus, chronic heart failure, and end-stage renal disease (requiring dialysis), among others.[20]
- **Waiver of "Primarily Health Related" Requirement:** The "primarily health related" standard, which ordinarily excludes coverage of supplemental benefits addressing social determinants of health (SDH), is waived for SSBCI.[21] Instead, plans have discretion to cover any service that bears a "reasonable expectation of improving and maintaining the health or overall function of the chronically ill enrollee."[22] CMS has explicitly listed as examples of potential SSBCI "food and produce to assist. . .in meeting nutritional needs."[23]
- **Waiver of Uniformity Requirement:** Congress also waived the uniformity requirement for SSBCI, allowing plans to tailor benefits to fit the unique clinical needs of each chronically ill enrollee. Notably, this waiver does not allow plans to target SSBCI to enrollees based solely upon social needs such as food insecurity.[24] CMS states that "plans may consider social determinants of health as a factor to help identify chronically ill enrollees whose health could be improved or maintained with SSBCI and they may use social determinants to further limit SSBCI eligibility. However, they may not use social determinants of health as the sole basis for determining eligibility for SSBCI."[25]

* Traditionally, acceptable general supplemental benefits include dental, vision, hearing, and preventative care benefits.

Medicare Advantage plans may thus cover produce prescriptions for chronically ill enrollees as SSBCI and may target these benefits to reach those enrollees who stand to benefit from them the most. Moreover, the Agency suggests that "an MA plan could elect to offer, as a SSBCI, the provision of meals or food/produce and *pay a community-based organization for furnishing the covered benefit*."[26] For the 2021 plan year, produce and food supports are among the most popular benefits provided under SSBCI, offered by 336 plans covering 1.9 million beneficiaries.[27]

Application Process for SSBCI

Plans may designate supplemental benefit packages as SSBCI when submitting their annual bids to CMS, typically due in June of the preceding calendar year. This information can be entered into section B-19 of the Plan Benefit Package (PBP) software program.[28]

VBID

The Medicare Advantage Value-Based Insurance Design or "VBID" model is a pilot program (extended until December 31, 2024) aimed at enhancing quality, improving access, and lowering costs.[29] To achieve these goals, the VBID model allows participating Medicare Advantage plans to waive a number of standard requirements, including those related to supplemental benefit delivery.[30] In particular, the VBID model waives both the primarily health related standard and uniformity requirement.[31] The program has steadily gained traction, now with over 451 participating plans covering 4.6 million beneficiaries nationwide.[32]

- **Requirements for Participation in VBID:** In order to participate in VBID a Medicare Advantage plan must meet certain requirements. Specific conditions may change somewhat between application cycles but in general plans must:
  (1) be either a coordinated care or special needs plan,
  (2) demonstrate a history of participation in Medicare Advantage, and
  (3) satisfy certain quality standards.[33]

- **Waiver of "Primarily Health Related" Requirement:** As with SSBCI, plans participating in VBID may provide supplemental benefits that are not "primarily health related," including produce prescriptions. CMS directly speaks to this in its Request for Applications, noting **"the additional non-primarily health related supplemental benefits that CMS will consider include, but are not limited to, meals (beyond the current allowable limits). . .and/or food and groceries."**[34] VBID also permits greater freedom in establishing new categories of chronically ill enrollees, including those not captured by the statutory definition, provided the plan explains how it will improve said enrollees' "health or overall functioning."[35,36]

- **Waiver of Uniformity Requirement:** The VBID model also waives the uniformity requirement. The extent of this waiver is different in the VBID model than in SSBCI. Going further than SSBCI, VBID allows for targeting enrollees on the basis of chronic illness, socioeconomic status—specifically eligibility for the low-income subsidy (LIS)**—or a combination of both.[37] Unlike SSBCI, VBID supplemental benefits must also be provided uniformly to all enrollees within the plan's chosen target population; they cannot be tailored to an individual enrollee.[38]

** Of note, beneficiaries deemed to qualify for LIS include those who (1) receive both Medicare and full Medicaid benefits, (2) receive supplemental security income from the Social Security Administration (SSA), (3) participate in the Medicare Saving Programs, or (4) independently apply to SSA or their state for LIS. For territories where LIS status is not available, plans are permitted to use dual Medicare and Medicaid eligibility status for targeting enrollees on the basis of socioeconomic status.

Application Process for VBID

VBID requires a separate annual application; however, many aspects of the applications are similar to streamline the process.

Conclusion

Traditionally, most nutritional interventions have not been eligible to receive coverage as Medicare Advantage supplemental benefits. This has changed in recent years, with Congress and CMS offering plans significant flexibility in designing novel benefit packages. Medicare Advantage plans may now offer produce prescriptions through either SSBCI or VBID pathways, depending on the intervention's anticipated focus. For example, one geared towards reaching chronically ill enrollees may be structured as an SSBCI intervention; a program aimed towards low-income beneficiaries could be more appropriately delivered through VBID.

Table 1. Summary of Supplemental Benefit Options

	Benefit Requirements	Eligibility	Timeline	Application to Produce Prescriptions
General Supplemental Benefits	1. Services not covered by Medicare Parts A or B 2. "Primarily health related" 3. Non-zero direct medical cost 4. Apply uniformly to all beneficiaries	• Cannot target enrollees on basis of socioeconomic status	• Submit bids by June of preceding calendar year	• Produce prescriptions likely not covered, as not "primarily health related"
SSBCI	1. Services not covered by Medicare Parts A or B 2. Enrollees must meet statutory definition of "chronically ill" 3. Non-zero direct medical cost***	• Chronically ill enrollees only • Cannot target enrollees solely on basis of socioeconomic status	• Submit bids by June of preceding calendar year	• Produce prescriptions covered
VBID	1. Services not covered by Medicare Parts A or B	• Can target enrollees on basis of chronic illness, socioeconomic status, or both	• Submit application during the preceding calendar year (typically March or April)	• Produce prescriptions covered • Pilot program, participation by application only

*** In the context of SSBCI, a non-zero direct medical cost means a non-administrative cost for providing the benefit. The cost incurred does not necessarily have to be a cost paid to a medical provider. *See* Ctrs. for Medicare & Medicaid Servs., Announcement of Calendar Year 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter 190 (2019), https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.

Endnotes

1 U.S. Dep't of Agriculture, Economic Research Service, *Definitions of Food Security*, USDA, https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/definitions-of-food-security/ (last visited Feb. 3, 2021).

2 Craig Gundersen & James P. Zilak, *Food Insecurity and Health Outcomes*, 34 Health Affs. 1830 (2015).

3 Haley Swartz, *Produce Rx Programs for Diet-Based Chronic Disease Prevention*, 20 AMA J. Ethics 960 (2018).

4 Seth Berkowitz et al., *Medically Tailored Meal Delivery for Diabetes Patients with Food Insecurity: A Randomized Cross-over Trial*, 34 J. Gen. Internal Med. 396 (2019).

5 Haley Swartz, *Produce Rx Programs for Diet-Based Chronic Disease Prevention*, 20 AMA J. Ethics 960 (2018).

6 Erika S. Trapl et al., *Dietary Impact of Produce Prescriptions for Patients with Hypertension*, Preventing Chronic Disease, Nov. 2018, at E138.

7 Margot B. Kushel et al., *Housing Instability and Food Insecurity as Barriers to Health Care Among Low-Income Americans*, 21 J. Gen. Internal Med. 71 (2006).

8 Victoria L. Mayer et al., *Food Insecurity, Coping Strategies and Glucose Control in Low-Income Patients with Diabetes*, 19 Pub. Health Nutrition 1103 (2016).

9 Richard Bryce et al., *Participation in a Farmers' Market Fruit and Vegetable Prescription Program at a Federally Qualified Health Center Improves Hemoglobin A1C in Low Income Uncontrolled Diabetes*, 7 Preventative Med. Reps. 176 (2017).

10 Victoria L. Mayer et al., *Food Insecurity, Coping Strategies and Glucose Control in Low-Income Patients with Diabetes*, 19 Pub. Health Nutrition 1103 (2016).

11 Haley Swartz, *Produce Rx Programs for Diet-Based Chronic Disease Prevention*, 20 AMA J. Ethics 960 (2018).

12 Richard Bryce et al., *Participation in a Farmers' Market Fruit and Vegetable Prescription Program at a Federally Qualified Health Center Improves Hemoglobin A1C in Low Income Uncontrolled Diabetes*, 7 Preventative Med. Reps. 176 (2017).

13 *Produce Prescriptions*, Reinvestment Partners, https://reinvestmentpartners.org/what-we-do/produce-prescriptions/ (last visited Feb. 3, 2021).

14 Jane Sung & Claire Noel-Miller, AARP, Supplemental Benefits in Medicare Advantage: Part I: An In-Depth Look At What They Are Today (2018), https://www.aarp.org/content/dam/aarp/ppi/2019/january-2019/supplemental-benefits-under-medicare-advantage-part-one.pdf.

15 Ctrs. for Medicare & Medicaid Servs., Implementing Supplemental Benefits for Chronically Ill Enrollees (2019), https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/Supplemental_Benefits_Chronically_Ill_HPMS_042419.pdf.

16 Ctrs. for Medicare & Medicaid Servs., Medicare Managed Care Manual Chapter 4 § 30.1 (2016) https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.

17 42 C.F.R. § 422.122(b)(3); Ctrs. for Medicare & Medicaid Servs., Medicare Managed Care Manual Chapter 4 § 30.3 (2016) https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.

18 Ctrs. for Medicare & Medicaid Servs., Medicare Managed Care Manual Chapter 4 § 30.3 (2016) https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.

19 42 U.S.C. § 1395w-22(a)(3)(D)(iii).

20 Ctrs. for Medicare & Medicaid Servs., Medicare Managed Care Manual Chapter 16-B § 20.1.2 (2016), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c16b.pdf.

21 42 U.S.C. § 1395w-22(a)(3)(D)(ii).

22 42 U.S.C. § 1395w-22(a)(3)(D)(ii).

23 Ctrs. for Medicare & Medicaid Servs., Implementing Supplemental Benefits for Chronically Ill Enrollees (2019), https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/Supplemental_Benefits_Chronically_Ill_HPMS_042419.pdf.

24 Ctrs. for Medicare & Medicaid Servs., Announcement of Calendar Year 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter 188 (2019), https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.

25 Ctrs. for Medicare & Medicaid Servs., Implementing Supplemental Benefits for Chronically Ill Enrollees (2019), https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/Supplemental_Benefits_Chronically_Ill_HPMS_042419.pdf.

26 Ctrs. for Medicare & Medicaid Servs., Announcement of Calendar Year 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter 190 (2019), https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.

27 Robin Duddy-Tenbrunsel et al., Avalere, MA Enrollment in Plans with Extra Benefits for Chronically Ill Tripled in 2021 (2020), https://avalere.com/insights/ma-enrollment-in-plans-with-extra-benefits-for-chronically-ill-tripled-in-2021.

[28] Ctrs. for Medicare & Medicaid Servs., Implementing Supplemental Benefits for Chronically Ill Enrollees (2019), https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/Supplemental_Benefits_Chronically_Ill_HPMS_042419.pdf.

[29] Ctrs. for Medicare & Medicaid Servs., Medicare Advantage Value-Based Insurance Design Model Calendar Year 2021 Model Participation (2020), https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-value-based-insurance-design-model-calendar-year-2021-model-participation; Ctrs. for Medicare & Medicaid Servs., Value-Based Insurance Design Model Fact Sheet CY 2021, https://innovation.cms.gov/files/fact-sheet/vbid-cy21-fs.pdf.

[30] 42 U.S.C. § 1395w-28(h).

[31] Ctrs. for Medicare & Medicaid Servs., Value-Based Insurance Design Model Fact Sheet CY 2021, https://innovation.cms.gov/files/fact-sheet/vbid-cy21-fs.pdf.

[32] Ctrs. for Medicare & Medicaid Servs., Medicare Advantage Value-Based Insurance Design Model Calendar Year 2021 Model Participation (2020), https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-value-based-insurance-design-model-calendar-year-2021-model-participation.

[33] *See, e.g.*, Ctrs. for Medicare & Medicaid Servs, Value-Based Insurance Design Model Request for Applications for CY 2022 25 (2021), https://innovation.cms.gov/media/document/cy-2022-vbid-rfa-final.

[34] *See, e.g.*, Ctrs. for Medicare & Medicaid Servs, Value-Based Insurance Design Model Request for Applications for CY 2022 13 (2021), https://innovation.cms.gov/media/document/cy-2022-vbid-rfa-final.

[35] 42 U.S.C. § 1395w-22(a)(3)(D)(iii).

[36] *See, e.g.*, Ctrs. for Medicare & Medicaid Servs, Value-Based Insurance Design Model Request for Applications for CY 2022 11 (2021), https://innovation.cms.gov/media/document/cy-2022-vbid-rfa-final.

[37] *See, e.g.*, Ctrs. for Medicare & Medicaid Servs, Value-Based Insurance Design Model Request for Applications for CY 2022 11-12 (2021), https://innovation.cms.gov/media/document/cy-2022-vbid-rfa-final.

[38] *See, e.g.*, Ctrs. for Medicare & Medicaid Servs, Value-Based Insurance Design Model Request for Applications for CY 2022 12 (2021), https://innovation.cms.gov/media/document/cy-2022-vbid-rfa-final.

About the Authors

The Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) advocates for legal, regulatory, and policy reforms to improve the health of underserved populations, with a focus on the needs of low-income people living with chronic illnesses. CHLPI works with consumers, advocates, community-based organizations, health and social services professionals, food providers and producers, government officials, and others to expand access to high-quality health care and nutritious, affordable food; to reduce health disparities; to develop community advocacy capacity; and to promote more equitable and effective health care and food systems. CHLPI is a clinical teaching program of Harvard Law School and mentors students to become skilled, innovative, and thoughtful practitioners as well as leaders in health, public health, and food law and policy.

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