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New Options in Medicare Advantage: Addressing the Social Determinants of Health and More

Over the last year, new laws, regulations, and guidance from the Centers for Medicare & Medicaid Services (CMS) have created a number of opportunities for Medicare Advantage (MA) plans to innovate on benefits and formularies. The new rules are primarily focused in three general areas:

- Reinterpretation of existing requirements that MA supplemental benefits be "primarily health related" allowing for **supplemental benefits for daily maintenance** in addition to those for the diagnosis, treatment and prevention of an illness or injury.
- Reinterpretation of existing uniformity rules and a new provision of law, allowing **certain supplemental benefits to be targeted to specific groups of enrollees**.
- **New coverage policies and utilization management opportunities** for prescription drug formularies.

Hospitals and health systems may be interested in discussing these new flexibilities with MA plans as part of collaborative efforts between providers and plans to improve the health of beneficiaries in their communities.

Background

Plans that wish to participate in the MA program are paid by Medicare based in part on their bids for estimated costs per enrollee relative to a bidding target known as the "benchmark." CMS sets a benchmark for each county (or region) according to a statutory formula.

If a plan's bid is lower than the benchmark, the plan and Medicare split the difference between the bid and the benchmark. The plan's share, known as a "rebate," is equal to a fixed percentage of the difference between the plan's actual bid and its risk-adjusted benchmark. Plans are required to use those rebates to provide lower cost sharing, lower premiums, or supplemental benefits to enrollees. Supplemental benefits can include supplemental drug coverage, a reduction in cost sharing and coverage of drugs not covered under Medicare Part D.

Under existing rules and guidance, supplemental benefits must be offered to all enrollees of a plan residing within a service area of the plan– a rule referred to as the "uniformity" requirement.[1] New flexibilities both in the interpretation of the "uniformity" principle and under the Bipartisan Budget Act of 2018 (BiBA) will allow some targeting of certain supplemental benefits to groups of enrollees of the plan. (See explanations of those new flexibilities below.)

Definition of Supplemental Benefits. A supplemental benefit is defined in Medicare guidance as an item or service that is:

1. Not covered by original Medicare;
2. Primarily health related; and
3. One which the MA plan must incur a non-zero direct medical cost.

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Prior to the new guidance detailed below, CMS required a supplemental service or item to be "primarily health related," to *diagnose, prevent, or treat* an illness or injury, compensate for physical impairments, act to ameliorate the functional or psychological impact of injuries or health conditions, or reduce avoidable emergency and health care use.

In addition, under rules applicable to MA contract year 2018 and prior years, a supplemental benefit must be *medically necessary* and additional to the benefit covered by original Medicare. For example, an MA plan can offer additional inpatient hospital days, but it cannot offer additional home health days if the Home Health Agency Manual has classified those additional days as not covered because they are not medically necessary.

The Medicare Managed Care manual provides a long list of ***examples*** of supplemental benefits including conditions for their coverage (e.g., must be provided by licensed or certified providers operating within their scope of practice). The manual also provides examples of benefits that cannot be considered supplemental benefits.

Examples of Acceptable Supplemental Benefits	• Additional days or sessions of Medicare covered services • Expansion of coverage for benefits for which an enrollee might not otherwise qualify • Acupuncture • Routine chiropractic services • Counseling services to diagnose and treat mental illness • Fitness benefits • Enhanced disease management[2] • Meals for a temporary duration • Nutritional/dietary education • Over-the-counter drugs • Personal emergency response system • Preventive benefits • Point-of-service option • Post-discharge in-home medication reconciliation • Remote access technologies • Telemonitoring services • Transportation services • Weight management programs • Worldwide emergency/urgent coverage
Examples of Unacceptable Supplemental Benefits	• Cosmetic services or surgery • Funeral expenses • Massage therapy • Maid services • Smoke detectors and fire extinguishers • Meals (unless otherwise specified)
Source: The Medicare Managed Care Manual	

Breadth of "Extra Benefits" Under Existing Rules. Supplemental benefits under MA consist mostly of services such as dental, vision and hearing coverage that are of more value to the sick than the healthy, rather than features such as gym memberships targeting the healthy. And because supplemental benefits are almost as prevalent in zero-premium MA plans as in plans that require an extra premium, they are available to lower-income Medicare beneficiaries.

In 2010, the Kaiser Family Foundation reported that a majority of MA plans offered at least one "extra benefit." Most commonly offered extra benefits include vision exams (86 percent), hearing tests (65 percent), worldwide health benefit (62 percent) and preventive dental (55 percent). The authors of the report use the Medicare Compare files for these data but indicate that those files do not include information about how individual plans define those benefits. So, for example, it isn't possible to know, based on the Medicare Compare data files, what is considered to be part of a "worldwide health benefit."[3]

New Benefits Flexibilities

The BiBA and new CMS rules and guidance describe a number of new options and flexibilities for MA and Medicare Prescription Drug (PD) plans beginning for plan years 2019 and 2020.

New Health-Related Supplemental Benefits. The contract year 2019 Call Letter and CMS rules finalized in June 2018 provide for a broader interpretation of "supplemental benefits" that allow for health care services for daily maintenance beginning with the calendar year (CY) 2019 plan year.[4] As detailed above, prior rules restricted supplemental benefits to those that were medically necessary and used to diagnose, treat, or prevent an illness or injury.

Under the new interpretation, CMS will continue to consider health care items or services to be primarily health related when they are used to diagnose, compensate for physical impairments; ameliorate the functional/psychological impact of injuries or health conditions; or reduce avoidable emergency and health care utilization. Beginning with the 2019 plan year, however, CMS indicates that it will interpret those conditions more broadly.

CMS provides examples of the new flexibility. It would allow, for example, an MA plan to offer an enrollee with diabetes benefits such as reduced cost sharing for endocrinology visits; more frequent foot exams as a supplemental benefit; or a lower deductible. For CMS to approve such a benefit, it must still focus directly on an enrollee's health care needs and be recommended by a licensed medical professional. CMS explicitly states that supplemental benefits under this new interpretation cannot be an item or service that is solely or primarily used for cosmetic, comfort, general use or social determinant purposes. Further, a plan still must design supplemental benefits in a non-discriminatory manner. The nondiscrimination rules protect high-acuity enrollees from adverse treatment on the basis of their higher cost health conditions. Thus, a plan would not be able to target cost-sharing reductions or additional supplemental benefits for a large number of disease conditions, while excluding other higher-cost conditions.

Examples of New Allowable Supplemental Benefits

- Adult day care services
- Home-based palliative care
- In-home support services to assist individuals with disabilities or other conditions in performing activities of daily living
- Support for caregivers such as respite or personal care attendants
- Medically-approved non-opioid pain management
- Home and bathroom safety devices and modifications
- Transportation
- Over-the-counter medication benefit

Source: Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Memorandum dated April 27, 2018 from Kathryn A. Coleman, Director of the Medicare Drug & Health Plan Contract Administration Group, CMS to Medicare Advantage Organization and Section 1876 Cost Contract Plans regarding Reinterpretation of "Primarily Health Related" for Supplemental Benefits.

New Flexibility to Target Benefits. Beginning in CY 2019, MA plans will be permitted greater flexibility to target a plan's benefits to a specific population among its enrollees tied to health status or a disease state.[5] CMS guidance provides that under the new rule, an MA plan will be able to:

- Reduce cost sharing or deductibles for certain covered benefits; or
- Offer specific tailored supplemental benefits for enrollees that meet specific medical criteria without violating uniformity rules.[6] MA organizations offering targeted benefits under this flexibility must do so for clearly identifiable clinical categories defined formally by ICD-10 codes and the benefits must be medically related to the disease state.

Examples of disease states that plans could target

- Diabetes or pre-diabetes
- Chronic obstructive pulmonary disease
- Congestive health failure
- Patient with past stroke, hypertension and coronary artery disease
- Lower back pain
- Kidney disease
- Obesity
- Asthma
- Tobacco use
- Hypercholesterolemia

Source: Memorandum dated April 27, 2018 from Kathryn A. Coleman, Director of the Medicare Drug and Health Plan Contract Administration Group, CMS to Medicare Advantage Organizations and Section 1876 Cost Plans, "Reinterpretation of the Uniformity Requirement."

CMS explicitly states, however, that *"Social determinants may not be used as a means to target benefits, even for those benefits related to health (e.g. homelessness, food insecurity.)"*[7]

Plans choosing to target benefits to a specific population tied to health status must provide that similarly situated enrollees (that is, all enrollees who meet the identified criteria) are treated the same way. The benefit and cost-sharing flexibility applies to MA benefits but not Part D benefits.

Under the new rule, non-uniform MA supplemental benefits can be offered as long as:

1. The MA organization ensures equal treatment of enrollees with the same clinical conditions;
2. The benefits are consistent with equal access and anti-discrimination provisions; and
3. The benefits are priced at a uniform premium consistent with the requirement for uniform bids and premiums.[8]

CMS believes this flexibility will help MA plans better manage health care services for particularly vulnerable enrollees.

Expanding Supplemental Benefits for Chronically Ill Enrollees. Under section 50322 of the BiBA, beginning with CY 2020 MA plans (including MA Special Needs Plans) will be permitted to provide additional supplemental benefits that are targeted to chronically ill enrollees. Under the provision, CMS is given the authority to waive the

uniformity requirement as it determines it is needed for the plan to provide the benefits to a MA plan's chronically ill enrollees. ***Supplemental benefits for chronically ill enrollees under the new provision are not limited to benefits that are primarily health related.*** The benefits must, however, have a reasonable expectation of improving or maintaining the health or overall function of the chronically-ill enrollee as under existing rules.

Chronically ill enrollees are defined as those who have one or more comorbid and medically complex chronic condition that:

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.

CMS indicates that additional guidance on this provision will be issued in advance of the 2020 contract year.

Expanding Telehealth Benefits for Chronically Ill Enrollees. For plan years before 2020, MA plans also are prohibited from including any additional telehealth services beyond those covered in original fee-for-service (FFS) Medicare as part of its basic benefit package. Benefits for additional telehealth services may be included as supplemental benefits. Supplemental benefits, however, must be paid for by the enrollee either through additional premium charges above the amounts for the basic MA benefit or with a rebate.

Pursuant to section 50323 of the BiBA, beginning in 2020, MA plans may offer "additional telehealth services" to chronically ill enrollees as part of the basic benefit package. These additional telehealth services will be permitted to be included in the plan bid for the basic benefit meaning the beneficiary will not have to pay a supplemental premium to access the services.

Additional telehealth services are Medicare Part B services that CMS identifies as clinically appropriate and include services not covered through the FFS telehealth benefit due to existing geographic, provider or technology restrictions. Under FFS Medicare, telehealth services are permitted only in certain, mostly rural geographic areas; may be provided only by certain providers; and may use only synchronous technologies. Store and forward asynchronous technologies, for example, are not permitted.

Under the BiBA provisions, the definition of chronically-ill enrollees is the same as described above. The legislation requires CMS to set conditions for plans to offer additional telehealth benefits, including physician/practitioner qualifications and training, and factors to coordinate these benefits with other items and services including those furnished in-person. In addition, CMS is required to seek stakeholder input on types of additional telehealth services that should be considered and other requirements that should apply. It has done so in proposed rules issued in October 2018.[9]

Beginning in 2020, there will be three different categories of supplemental benefits:

1. **Standard. Offered to all enrollees;**
2. **Targeted. Offered only to qualifying enrollees by health status or disease state; and**
3. **Chronic. Offered to enrollees who are chronically ill (defined above).**

Standard and targeted supplemental benefits must meet the existing requirement that they be "primarily health related" although primarily health related will be more liberally defined to allow for ongoing maintenance per recent rules and guidance. Chronic supplemental benefits must have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee.

Insofar as MA plans offer additional telehealth services for chronically-ill enrollees, the plans also must provide coverage for those services furnished through an in-person visit; and enrollees must have the option to receive the additional benefit through telehealth or in person.

Enhanced Disease Management (EDM) for Dual Eligible Special Needs Plans (D-SNPs) and Institutionalized Special Needs Plans (I-SNPs). CMS is allowing, beginning with the 2019 plan year, for additional flexibility in providing supplemental EDM services as well. As described in the 2019 MA and Part D Final Notice and Call Letter, D-SNPs and I-SNPs may offer the EDM supplemental benefit that is currently available only to non-SNP MA plans. A supplemental EDM benefit is described in CMS guidance as providing for qualified case managers with specialized knowledge about the target disease(s)/condition(s), educational activities that are focused on the target disease(s)/condition(s), and routine monitoring applicable to the target disease(s)/ condition(s).[10]

Chronic Condition SNPs (C-SNPs) are not affected because they must already have a comprehensive targeted disease management program in order to receive designation as a C-SNP.

New Formulary Flexibilities

CMS has issued proposed rules and guidance that would provide MA plans with additional flexibility to apply certain utilization management tools to covered prescription drug benefits. Those actions would allow plans to apply step therapy to covered Part B drugs and to implement indication-based formulary designs and utilization management strategies.

Step Therapy for Part B Drugs. CMS has rescinded its 2012 guidance prohibiting MA plans from using step therapy as a utilization management tool for Part B drugs.[11] Under the new guidance and proposed regulatory amendments, beginning Jan. 1, 2019, MA plans are able to incorporate step therapy, an approach to utilization management that requires a person to begin medication for a condition with a preferred drug therapy and progress to other therapies only if necessary.[12]

MA organizations continue to be subject to statutory requirements to provide access to all Part A and Part B benefits available in original FFS Medicare and to provide coverage consistent with national coverage decisions. CMS indicates that all enrollees subject to a Part B step therapy limit must be offered participation in a drug management care coordination program. CMS indicates that drug management care coordination activities in this context, include at least the following:

- Interactive medication review and associated consultations for enrollees to discuss all current medications and perform medication reconciliation and follow-up when necessary;
- Educational materials and information to enrollees about drugs within the drug management care coordination program; and
- Medication adherence strategies to help enrollees with their medication regimen.

To assure that step therapy requirements don't disrupt ongoing care for people who are being treated with other prescriptions, step therapy under the new guidance can be applied only to new prescriptions or administrations of Part B drugs for enrollees. An enrollee who already is receiving a particular drug under Part B cannot be required under a step therapy program to change their medication.

Indication Based Formulary Design and Utilization Management. On July 25, 2018, CMS issued guidance allowing Part D plan sponsors to use indication-based utilization management strategies in Part D. August

guidance further expands on indication-based approaches to allow sponsors to include indication-based formulary designs beginning in CY 2020.[13]

Current CMS policy requires that each on-formulary drug be covered for all indications that are approved by the Food & Drug Administration (FDA), except for those statutorily excluded from Part D coverage.[14] Under the July guidance, Part D sponsors can use step therapy-like requirements within their prior authorization programs to require the use of one formulary drug for a certain indication prior to authorizing coverage of another drug for that indication.

Building on the new flexibility, CMS will allow, starting for CY 2020, Part D sponsors to implement indication-based formulary designs that tailor on-formulary coverage of drugs based on specific indications. Under this approach plans will be able to negotiate formulary coverage based on specific indications, and consider only certain indications to be on-formulary for a given drug. CMS states that this would enable them to better negotiate for prescription drugs, especially high-cost drugs, because the ability to exclude drugs from their formulary for specific indications will provide additional negotiating leverage with manufacturers.

Guidance provides that if a Part D sponsor limits on-formulary coverage of drugs to certain indications, it must ensure that there is another therapeutically similar drug on formulary for the non-formulary indication. CMS provides an example of a tumor necrosis factor (TNF) blocker that is FDA-approved for both Crohn's disease and plaque psoriasis. Under this flexibility, a plan sponsor could include it on the formulary only for plaque psoriasis. In this case the plan must cover another TNF blocker on its formulary for Crohn's disease. Otherwise, the plan design may not meet anti-discrimination requirements. All other existing formulary requirements would continue to apply.

Sources

1. Under existing rules, supplemental benefits, premiums or cost sharing could vary among services areas of a plan and premiums and cost sharing can also vary among segments of a plan.
2. See section below describing new flexibilities below for the provision of enhanced disease management.
3. Gold, M., et al., Medicare Advantage 2010 Data Spotlight: Benefits and Cost-Sharing, Kaiser Family Foundation, February 2010, https://kaiserfamilyfoundation.files.wordpress.com/2013/01/8047.pdf.
4. Medicare Program: Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program [Final Rule CMS-4182-F].
5. CMS-4182-F.
6. Memorandum dated April 27, 2018 from Kathryn A. Coleman, Director of the Medicare Drug and Health Plan Contract Administration Group, CMS to Medicare Advantage Organizations and Section 1876 Cost Plans, "Reinterpretation of the Uniformity Requirement." https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Weekly-Items/SysHPMS-Memo-2018-Week4-Apr-23-27.html?DLPage=4&DLEntries=10&DLSort=1&DLSortDir=descending.
7. CDC described the social determinants of health, or the social factors that impact a person's state of health, to include factors such as their social and physical environments, where and how a person lives, their income, gender and whether they're subject to discrimination.
8. See Sections 1852 and 1854(c) of the Social Security Act.
9. Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 (CMS-4185-P), 83 Federal Register 54982.
10. Section 30.3 of Chapter 4 of the Medicare Managed Care Manual. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.
11. Memorandum dated August 7, 2018 from Seema Verma, Administrator, to Medicare Advantage Organizations, "Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage," https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf.
12. Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P), 83 Federal Register 62152.
13. Memorandum dated July 25, 2018 to All Part D Sponsors from Seema Verma, Administrator, "Indication-Based Utilization Management."
14. Memorandum dated August 29, 2018 to All Part D Sponsors from Seema Verma, Administrator, "Indication-Based Formulary Design Beginning in Contract Year (CY) 2020."