

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 3 - I-08

Subject: Payment for Biologic and Pharmacologic Agents

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Referred to: Reference Committee J
(Jack J. Beller, MD, Chair)

1 At the 2007 Interim Meeting, the House of Delegates adopted as amended Resolution 721,
2 “Biologic Payments.” The first Resolve of Resolution 721 (I-07) asked that the American Medical
3 Association (AMA) study the inability of practicing physicians to obtain payment (including drugs
4 and their managerial acquisition costs) for biologics and pharmacologic agents at the rates intended
5 by Congress. The Board of Trustees assigned the requested study to the Council on Medical
6 Service for a report back to the House at the 2008 Interim Meeting.

7
8 This report describes coverage and payment of biologic and pharmacologic agents, reviews the
9 impact of the average sales price (ASP) payment system on physician practices, discusses the
10 viability of the competitive acquisition program (CAP) as an alternative to the ASP-based payment
11 system, identifies trends in patient access to care, outlines related AMA advocacy and policy, and
12 presents policy recommendations.

13 14 COVERAGE AND PAYMENT OF BIOLOGIC AND PHARMACOLOGIC AGENTS

15
16 Medicare Part B covers a limited set of drugs that are furnished and administered as part of a
17 physician service. Biologics, also called biotech drugs, or biopharmaceuticals, are derived from
18 living sources such as humans, animals or microorganisms and are often categorized as specialty
19 pharmaceuticals. A “biological product” is defined under the Public Health Service Act as “a
20 virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic
21 product, or analogous product . . . applicable to the prevention, treatment or cure of a disease or
22 condition of human beings.” (PHS Act §351(i), 42 U.S.C. §262(i)). Medicare Part B also covers a
23 limited number of other types of drugs, including durable medical equipment (DME) supply drugs,
24 physician-administered chemotherapy, immunosuppressant drugs, some oral anti-cancer drugs, oral
25 anti-emetic drugs, erythropoietin (EPO), some vaccines, and parenteral nutrition.

26
27 The complexity and cost of production for biologics is far greater than that for traditional drugs.
28 These drugs represent a growing segment of the US drug industry and an escalating health care
29 expenditure. Medicare expenditures for Part B drugs grew rapidly between 1997 and 2003, rising
30 from \$2.8 billion to \$10.3 billion. In response to a series of governmental reports and hearings
31 indicating that Medicare payments for many of these drugs greatly exceeded physician acquisition
32 costs, the payment methodology for Part B covered drugs was revised through the Medicare
33 Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), and phased in beginning
34 in 2004. The MMA resulted in a payment decrease for Medicare Part B drugs from 95% of the
35 average wholesale price (AWP) to 106% of the average sale price (ASP). The ASP for a given
36 product is the weighted average of pharmaceutical manufacturers’ sales prices, including discounts,
37 and is based on these transaction prices from the previous two quarters.

1 IMPACT OF THE AVERAGE SALE PRICE (ASP) ON PHYSICIAN PRACTICES

2
3 Even before implementation of the ASP-based payment system, there were concerns about its
4 ability to ensure physician payment at a rate that consistently covers all of the acquisition and
5 administration costs associated with Part B drugs. When an oncology clinic purchases a cancer
6 drug, it incurs several costs above and beyond the acquisition costs of the drug, such as costs for
7 refrigeration and other specialty storage and equipment, inventory, billing and reimbursement
8 processing, pharmacy services, overhead and management, and waste. The Community Oncology
9 Alliance has calculated that for every \$100 in drug acquisition cost, an additional \$12 goes toward
10 paying costs associated with the drug. Accordingly, in order to simply break even, community
11 oncology clinics would need 12% above their acquisition cost, or approximately 112% of ASP.
12

13 In its January 2007 report, "Impact of Changes in Medicare Payments for Part B Drugs," the
14 Medicare Payment Advisory Commission (MedPAC) identified four common concerns that have
15 occurred since implementation: delays in payment, gaps between manufacturers' reported ASP and
16 the average physician purchase price, the ASP's failure to include costs associated with state and
17 local taxes, and price bundling.
18

19 Because the ASP payment rate is based on the transaction prices from the previous two quarters,
20 there is a delay in adjustment of the Medicare payment rate. The delay affects physicians most
21 often when a price for a specific drug has been increased, but the ASP-based payment is still at a
22 lower price. Gaps occur between manufacturers' reported ASP and the average physician purchase
23 price when the ASP includes volume discounts or other price concessions that are not normally
24 available to physicians, or when the ASP includes wholesale fees that physicians pay. When such
25 price and cost disparities occur, the ASP-based payment may be lower than the average physician
26 purchase price. In some parts of the country, physicians have reported that they pay state or local
27 taxes on Part B drugs, including sales tax and a tax on gross receipts, even though these costs are
28 not reflected in the ASP. Bundling occurs when a manufacturer offers provider discounts for one
29 of their products contingent on purchases of one or more other products. While price bundling
30 arrangements can result in lower payment rates for individual drugs, it can also compromise the
31 ability of physicians to choose products solely based on clinical factors. There is often a
32 requirement to buy a greater volume of one drug than is necessary in order to receive the bundled
33 discount for another drug. In addition, there are bundling discounts that can only be attained by
34 large practices, which can meet volume purchasing requirements of both drugs.
35

36 The ASP is calculated in a manner that includes discounts, including those for bulk purchases, from
37 which small physician practices have difficulty benefiting. Some discounts are not passed on to the
38 physician, but may be provided by the manufacturer to an HMO, a wholesaler or another
39 distributor. MedPAC reported that the physicians it surveyed consistently responded that large
40 practices were better able to negotiate lower drug prices and achieve economies of scale in their
41 practices relative to smaller practices. For example, prompt-pay discounts are only available to
42 those practices that can afford to buy the necessary volume of drugs in a timely fashion. This
43 disparity jeopardizes the livelihood of smaller practices and impacts access to care since more than
44 50% of physician practices have five physicians or less and account for 80% of outpatient visits.
45

46 In addition, according to MedPAC, certain specialties that routinely administer biologics have been
47 particularly hard hit, including oncologists, urologists, and infectious disease specialists. MedPAC
48 reported that urologists and infectious disease specialists provided fewer physician-administered
49 drugs in their offices in 2005 than in 2004. Physicians, particularly oncologists, reported spending

1 considerable time and staff resources seeking the best prices for drugs to try to secure patients'
2 drugs at ASP-based payment rates. Urologists and oncologists have the additional complication of
3 the "least costly alternative" policy, which applies to payment rates for certain drugs and further
4 complicates problems with ASP rates for these specialties.

5 6 COMPETITIVE ACQUISITION PROGRAM (CAP)

7
8 As required by the MMA, in 2005 the Centers for Medicare and Medicaid Services (CMS)
9 developed and implemented the Competitive Acquisition Program (CAP), which was designed to
10 be a voluntary alternative to the ASP-based payment system. CAP was intended to provide an
11 alternative method for physicians to obtain Part B drugs to administer to their Medicare patients
12 and to reduce drug acquisition and billing burdens for physicians. Through the CAP, participating
13 physicians are able to obtain Part B drugs from a vendor who purchases large quantities of drugs
14 and uses its bargaining power to negotiate lower prices from manufacturers. However, it is
15 questionable if CAP is a viable alternative to the ASP-based payment system due to limited vendor
16 options and overly restrictive and administratively burdensome elements of the program.

17
18 The sole preliminary CAP vendor, BioScrip, Inc., has remained the only vendor since
19 implementation. In the early months of the program BioScrip, Inc. outlined structural barriers that
20 affected physicians' decisions to participate in the program, along with potential solutions. The
21 most frequently cited barriers that physicians reported to BioScrip, Inc. included the lack of on-site
22 inventory, the requirement to ship to location, burdensome claims processing, concerns with
23 collecting beneficiary co-payments, and the limited election period. Recently, BioScrip, Inc. has
24 announced its decision not to renew its CAP contract with CMS for 2009, citing that the proposed
25 terms of the contract present profit risks for the company.

26
27 Since implementation in 2006, changes have been made and proposed to the CAP program to
28 address some of the initial concerns from physicians. In 2008, new and updated regulations
29 eliminated some of the administrative burdens. CAP drug administration claims can now be filed
30 within 30 days of administering CAP drugs; participating CAP physicians may now request to
31 leave the CAP within the first 60 days of election if program participation results in any burden to a
32 practice (e.g., difficulty meeting CAP drug ordering or billing requirements); and after 60 days, a
33 participating CAP physician may request to leave the CAP if an unexpected change in
34 circumstance results in CAP participation becoming a burden to a practice (e.g., a change in patient
35 population or practice personnel). Additional election periods have also been added. In addition,
36 in the proposed rule outlining revisions to payment policies under the physician fee schedule and
37 revisions to Part B in 2009, CMS has proposed a number of changes regarding the annual CAP
38 vendor payment amount update and the restriction on physician transportation of CAP drugs. CMS
39 is now proposing to ease the restrictions on physician transport of CAP drugs to settings other than
40 a participating CAP physician's office.

41
42 Even with these changes, key barriers to physician participation in CAP persist. A continued
43 concern is the post-payment review process, which includes both verification of drug
44 administration and medical necessity. This review process is unduly burdensome for physicians
45 and conflates two separate and distinct processes. While verifying administration is a relatively
46 straightforward post-payment process, undergoing a verification process that includes
47 documentation of both administration and medical necessity significantly expands the scope of the
48 audit and the records that need to be generated.

1 It is unclear how the planned and proposed changes will affect physician participation and
2 satisfaction with CAP. BioScrip, Inc. reported that initial physician participation levels in CAP
3 were significantly lower than the expected program target of 1,500 to 2,000 physicians. In the first
4 month, July 2006, there were a total of 307 CAP physicians, representing 664 practice locations.
5 Physician specialties with the highest Medicare Part B allowed charges for physician-administered
6 drugs had the lowest participation rates. Currently, CMS reports that 4,200 physicians are
7 participating in the CAP program out of a potential 200,000.

8
9 Most recently, CMS announced the postponement of the 2009 CAP. The current program will
10 continue through December 31, 2008. CMS reported “contractual issues” as the reason for
11 postponement and will solicit feedback from participating physicians, potential vendors and other
12 interested parties before proceeding with another contractor bid solicitation.

13 14 ACCESS TO CARE

15
16 While the full impact of the ASP-based payment system on access to care remains undetermined,
17 trends have started to develop. Some physicians have resorted to referring patients without
18 supplemental insurance, who might not be able to afford the significant co-payment, to hospital
19 outpatient departments for treatment. However, starting January 2008, some Medicare Part B
20 drugs administered in hospital outpatient settings have been reduced from 106% to 105% of ASP.
21 In addition, private payers often follow Medicare policy changes, which appears to be the case with
22 Medicare’s shift to an ASP-based payment system for Part B drugs. According to a 2007 survey
23 conducted by the Zitter Group, one third of commercial organizations reported using 106% of ASP
24 to reimburse oncologists. It is predicted that most health plans will move to ASP over the next few
25 years.

26
27 With the combination of inadequate physician and hospital outpatient payment rates, private payers
28 adopting ASP-based payment rates, and the exorbitant cost of many biologics, patient access to
29 care is threatened. One solution being considered by Congress is the establishment of an
30 abbreviated regulatory procedure for licensing “follow-on biologics” (FOBs), or generic forms of
31 biologics, by the Food and Drug Administration (FDA). The Congressional Budget Office (CBO)
32 estimates that enactment of an abbreviated procedure would reduce total expenditures on biologics
33 in the US by about \$25 billion over the next ten years. Savings to public and private purchasers of
34 biologics is expected as a result of the availability of these lower-priced versions.

35 36 AMA ADVOCACY AND POLICY

37
38 The AMA attempted to mitigate the impact of the MMA provisions during both the legislative and
39 regulatory processes. When legislation was first introduced to reduce Medicare payment for these
40 drugs, the AMA initiated a joint letter with 16 other organizations that, among other things, urged
41 legislators to consider “additional adjustments...to protect physicians with above-average costs”
42 and to include increases in payments for drug administration codes to offset cuts in payments for
43 the drug product. The AMA emphasized these same points in meetings with key congressional
44 staff and members, and was instrumental in the addition of language in the MMA that directed
45 CMS to develop new current procedural terminology (CPT) codes and relative value units (RVUs)
46 to improve payments for drug administration. The AMA then worked through the CPT Editorial
47 Panel and the AMA/Specialty Society Relative Value Scale Update Committee (RUC) to develop
48 and value the new codes on an expedited schedule.

1 In 2004 the AMA formed a work group for the specialties that administer Part B drugs with the
2 goal of moderating the payment cuts and easing the 2005 implementation of the ASP system. The
3 work group created a survey instrument for the affected specialties to identify problems in the early
4 implementation of the drug payment cuts. The results of the survey were used in AMA comments
5 on the proposed rule. The AMA commented to CMS on each regulation that involved the new
6 codes and/or payment policies. Specifically, the AMA repeatedly highlighted the provisions in the
7 MMA that could be interpreted to permit exceptions for certain practices or drugs that are difficult
8 for small practices to purchase at the ASP price. In 2005, when CMS issued a proposed rule to
9 implement the CAP for Medicare Part B drugs, the AMA convened a meeting for involved
10 specialties to convey concerns directly to the CMS officials responsible for writing the rules and
11 also provided comments outlining recommendations for the implementation and administration of
12 the program.

13

14 In August 2007, the AMA submitted a comment letter to CMS regarding the ASP-based payment
15 system and the CAP program, which reiterated the AMA's concern that the ASP-based payments
16 for covered Part B drugs were not sufficient to cover the actual cost of acquiring and administering
17 these drugs. The AMA again urged CMS to exercise its discretion to ensure that the new ASP-
18 based payment system did not systematically underpay small physician practices or particular
19 specialties. Since then, CMS has proposed a method to allocate bundled discounts in order to more
20 closely approximate actual prices. The total amount of price concessions would be allocated to the
21 various products involved in proportion to the sales of each drug sold under the bundled
22 arrangement. However, the AMA has informed CMS that this solution is not sufficient to address
23 the serious consequences of the existing ASP policy. The August 2007 comment letter also
24 addressed the post-payment review process used in CAP, the transportation of CAP drugs, CAP
25 election agreements, and contractual provisions with CAP vendors, among others issues.

26

27 The AMA supports legislative efforts to ensure that Medicare payments for drugs fully cover the
28 physician's acquisition, inventory and carrying cost and that Medicare payments for drug
29 administration and related services are adequate to ensure continued patient access to outpatient
30 infusion services, consistent with Policy D-330.960 (AMA Policy Database). In addition, the
31 AMA has worked to ensure that infusion supervision codes appropriately reflect the complexity of
32 the infusion service rendered, and that there are sufficient relative value units to such service
33 provided, as well as attendant practice expense, so that patient access to infusion therapies remains
34 uninterrupted, consistent with Policy D-70.970.

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36 AMA policy supports adequate reimbursement for vaccines and their administration from all public
37 and private payers and encourages health plans to recognize that physicians incur costs associated
38 with the procurement, storage and administration of vaccines that may be beyond the average
39 wholesale price (AWP) of any one particular vaccine (Policies D-440.989 and D-440.981). To
40 assist patients with access to biologics, AMA policy also supports complete transparency of health
41 care coverage policies related to biologics or specialty pharmaceuticals, including co-payment or
42 co-insurance levels and how these levels are determined (Policy H-185.953).

43

44 DISCUSSION

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46 Physicians who administer Part B drugs have experienced varying degrees of impact as a result of
47 the ASP-based payment change. ASP payments for Part B drugs are not always sufficient to cover
48 acquisition and administration costs. Certain specialties and practice sizes have been more
49 adversely affected than others. CAP has not succeeded in providing a viable alternative to the

1 ASP-based payment system. The Council believes that aspects of both the ASP-based payment
2 system and the CAP could be improved upon in order to rectify physicians' ability to practice and
3 ensure patient access to care. Given extensive AMA activity to mitigate the impact of the MMA
4 provisions during both the legislative and regulatory processes, the Council believes that the AMA
5 should continue its strong advocacy efforts working with national medical specialty societies to
6 ensure adequate physician payment for Part B drugs and patient access to biologic and
7 pharmacologic agents.

8
9 In preparation of this report, several specialties that have been disproportionately affected by the
10 Medicare Part B payment change were invited to comment. The American Society of Clinical
11 Oncology (ASCO) responded that it supports H.R. 3011, "Revision of Payment Methodology for
12 Drugs and Biologicals under Medicare Part B," which calls for CMS to be given the authority to
13 increase ASP payment "for a drug or biological to the extent necessary to ensure that such payment
14 amount is in no case less than the widely available market price (WAMP) for the drug or
15 biological." WAMP is defined as the price a "prudent physician or supplier would pay for the
16 drug."

17
18 H.R. 3011 addresses the limitations of CMS to independently interpret or modify the ASP-based
19 payment system. Since the ASP-based payment system was legislated through the MMA, CMS
20 has stated that it cannot make any exceptions to payments in the absence of new legislation. The
21 AMA is in communication with ASCO regarding issues of importance to oncologists and their
22 patients and supports its efforts to ensure that drug payments cover physicians' costs. The Council
23 believes that this activity demonstrates a productive working relationship and that the AMA should
24 continue collaborative efforts on this issue. As such, the Council suggests reaffirming existing
25 Policy D-330.960, which directs the AMA to actively support legislative efforts to ensure that
26 Medicare payments for drugs fully cover the physician's acquisition, inventory and carrying cost
27 and that Medicare payments for drug administration and related services are adequate to ensure
28 continued patient access to outpatient infusion services.

30 RECOMMENDATIONS

31
32 The Council on Medical Service recommends that the following be adopted and that the remainder
33 of the report be filed:

- 34
35 1. That our American Medical Association reaffirm Policy D-330.960, which directs the AMA to
36 actively support legislative efforts to ensure that Medicare payments for drugs fully cover the
37 physician's acquisition, inventory and carrying cost and that Medicare payments for drug
38 administration and related services are adequate to ensure continued patient access to
39 outpatient infusion services. (Reaffirm HOD Policy)
40
41 2. That our AMA continue strong advocacy efforts working with relevant national medical
42 specialty societies to ensure adequate physician payment for Part B drugs and patient access to
43 biologic and pharmacologic agents. (Directive to Take Action)

Fiscal Note: Staff cost estimated to be less than \$500 to implement.

References are available from the AMA Division of Socioeconomic Policy Development.