

## REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 4 - I-06  
(November 2006)

Subject: Health Plan Treatment of Specialty Pharmaceuticals

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1 At the 2005 Interim Meeting, the House of Delegates adopted as amended the recommendations in  
2 Council on Medical Service Report 2 (I-05), "Health Insurance Coverage of Specialty  
3 Pharmaceuticals." Recommendation 4 of the report calls on the AMA to "continue to monitor  
4 health plan treatment of specialty pharmaceuticals to ensure patient access to needed  
5 pharmaceuticals, and report back to the House of Delegates at the 2006 Interim Meeting." The  
6 Board of Trustees referred this directive to the Council on Medical Service.

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8 The intent of Council on Medical Service Report 2 (I-05) was to explore the effects of tiered  
9 pharmaceutical benefits on patients who require costly specialty pharmaceuticals for their  
10 treatment. The report highlighted trends associated with the availability, cost, and utilization of  
11 specialty pharmaceuticals; examined the use of tiered formularies; and explored other alternatives  
12 for managing the high cost of specialty pharmaceuticals. The report concluded that balancing the  
13 therapeutic value of specialty pharmaceuticals against treatment costs would be a new challenge for  
14 the health care industry, and that ensuring patient access to appropriate therapies must remain a  
15 priority.

16  
17 The term "specialty pharmaceutical" generally refers to specialized drugs used to treat a variety of  
18 serious and chronic conditions such as cancer, multiple sclerosis, rheumatoid arthritis, and  
19 hemophilia. Many specialty pharmaceuticals are subject to specific handling and distribution  
20 requirements, and often need to be administered by injection or infusion. These types of drugs tend  
21 to be extremely expensive because, in addition to their unique handling requirements, their  
22 development costs are high and few therapeutic or generic alternatives exist.

23  
24 Efforts by the health insurance industry to come to terms with the economic aspects of the rapid  
25 expansion of the specialty pharmaceutical market are ongoing. Many insurers are moving beyond  
26 the traditional method of controlling the unit costs of these drugs to examining a wide variety of  
27 variables associated with their use, including utilization patterns, dosing and administration  
28 requirements, and clinical factors. It is unclear how these efforts will ultimately affect patient  
29 access. Nevertheless, the Council believes it is important for physicians to be aware of some key  
30 areas that are the focus of specialty pharmaceutical cost management strategies. Accordingly, this  
31 report, which is presented for the information of the House, outlines issues associated with tracking  
32 and analyzing specialty drug utilization data; examines the use of specialty pharmacies; and  
33 summarizes new information about the use of drug formularies. The report also includes a section  
34 about the current status of specialty pharmaceuticals under Medicare Part D plans.

1 THE GROWTH OF SPECIALTY PHARMACEUTICALS

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3 As described in Council on Medical Service Report 2 (I-05), health insurers and employers are  
4 beginning to focus particular attention on specialty drugs because, in addition to being extremely  
5 expensive, industry experts report a consistent increase in the utilization of and spending on these  
6 products. According to the 2006 Medco Drug Trend Report, spending on specialty drugs grew  
7 nearly 17% in 2005, more than three times the average for drug spending overall. Projections  
8 suggest that over the next several years a significant number of new specialty drugs will be  
9 approved for an increasing array of medical conditions, thus expanding the market for these high  
10 priced therapies. Although less than 3% of patients use specialty pharmaceuticals, the pharmacy  
11 benefit manager Express Scripts estimates that these drugs account for 19% of total pharmaceutical  
12 spending, and projects the amount to increase to 28% by 2009 (Express Scripts, 2006).

13  
14 TRACKING SPECIALTY PHARMACEUTICALS UTILIZATION

15  
16 There is widespread agreement that specialty pharmaceuticals have the potential to change the way  
17 physicians and patients manage an expanding variety of chronic, severe, or even life-threatening  
18 conditions. There is also agreement that the explosive growth of these therapies, along with the  
19 corresponding increasing share of overall health care costs, will necessitate the development of a  
20 new framework within the health care industry to manage their utilization. Because the market for  
21 specialty pharmaceuticals is expanding so rapidly, many insurers have been caught off guard in  
22 terms of implementing administrative processes that facilitate tracking costs, utilization, and  
23 outcomes.

24  
25 As discussed in Council on Medical Service Report 2 (I-05), specialty pharmaceuticals traditionally  
26 have been billed under the medical portion of a patient's health insurance, rather than through a  
27 pharmaceutical benefit. Under this system, physicians generally purchase and maintain an  
28 inventory of the necessary drugs, and then bill a patient's insurance company under the J-code  
29 billing format at a rate that combines the cost of the drug, along with the fee for the office visit and  
30 the drug administration costs. From an insurer's perspective, this billing format lacks specificity  
31 that may be useful to its efforts to track trends in specialty drug usage, such as details about  
32 manufacturer, dosage, and product strength. In addition, because all the billing is post-service  
33 delivery, insurers are becoming increasingly concerned that they have little opportunity to  
34 prospectively influence utilization patterns through traditional methods such as prior authorization  
35 or specific formulary requirements.

36  
37 With the increasing availability of specialty therapies, especially those that can be self-  
38 administered, many insurance companies are funneling more claims through the pharmaceutical  
39 benefit, which allows them to better isolate details about drug costs, and maximize opportunities to  
40 manage utilization. According to one survey, 16% of health plans had already shifted coverage  
41 from the medical to the prescription-drug benefit, and an additional 28% planned to do so within  
42 the next year (JPMorgan/MedPanel Medical Directors Survey, 2004).

43  
44 Many insurers also believe that the variety of distribution channels for specialty pharmaceuticals  
45 compromises data tracking capabilities, and results in lost opportunities for effective specialty drug  
46 management. A 2005 report produced by the specialty pharmacy CuraScript identified three  
47 primary distribution channels for specialty drugs: physician office (45%); retail pharmacy (25%);  
48 and specialty pharmacy (15%). Patients also may be able to obtain drugs through clinics, regular

1 mail order, or local retail pharmacies. The multiplicity of distribution channels makes it difficult  
2 for insurers to obtain aggregate usage data and draw meaningful conclusions about ways in which  
3 efficiencies could be realized.

4  
5 PHARMACY BENEFIT MANAGERS AND SPECIALTY PHARMACIES

6  
7 For several years, health insurers have contracted with pharmacy benefit managers (PBMs) to  
8 administer pharmaceutical benefits for their plan enrollees. PBMs are responsible for negotiating  
9 drug prices with retail pharmacies and drug manufacturers on behalf of the plans, operating  
10 independent mail-order pharmacies, and managing other features of the benefit, such as claims  
11 adjudication, formulary design, and supervising prior authorization or other utilization management  
12 processes. A 2004 analysis conducted by PricewaterhouseCoopers estimated that 68% of the US  
13 population is covered by private insurance plans that utilize a PBM.

14  
15 Recently, the next generation of PBMs has evolved in the form of specialty pharmacies. Recent  
16 mergers in the specialty pharmacy market have led to a consolidation of the industry. Most  
17 specialty pharmacy business is operated by large PBMs (e.g., Medco or Express Scripts) or  
18 retailers, like Wal-Mart and CVS. Specialty pharmacies focus exclusively on the supply and  
19 distribution of specialty drugs, and thus claim to be able to offer several advantages over a  
20 traditional pharmacy relative to costs, data tracking, inventory management, and patient-care  
21 services.

22  
23 In addition to being able to negotiate price discounts because of volume purchasing, specialty  
24 pharmacies are actively marketing several other services that they argue may ultimately lower  
25 pharmaceutical costs. For example, specialty pharmacies are able to supply and manage drugs  
26 across multiple settings, which can assist in eliminating inefficiencies related to disparate billing  
27 and distribution practices. Another level of fragmentation may be eliminated if the pharmacy  
28 serves as the primary or only source of drug distribution. Because specialty pharmacies are  
29 dedicated exclusively to the provision of specialty drug products, they claim to be able to maintain  
30 expansive inventories that help to ensure that most patient needs can be met through the single  
31 vendor. Finally, specialty pharmacies emphasize their unique ability to offer personalized care  
32 management. Because the efficacy of many specialty pharmaceuticals is highly dependent on  
33 individual needs - from timing to dosage to frequency - specialty pharmacies distinguish  
34 themselves from traditional pharmacies by offering services that help maximize therapeutic benefit  
35 while minimizing waste.

36  
37 SPECIALTY FORMULARIES

38  
39 Specialty pharmacies also may offer guidance on the development of effective specialty  
40 formularies. Council on Medical Service Report 2 (I-05) presented information about the small but  
41 increasing number of health plans that are introducing drug formulary tiers reserved specifically for  
42 expensive specialty or biotech drugs. In addition to clustering specialty drugs into a distinct tier  
43 with higher patient cost-sharing, insurers are identifying ways to achieve cost savings by  
44 distinguishing between medications within a given therapeutic class. As specialty drugs have  
45 become more widely available, increasing numbers of therapeutic alternatives have been identified  
46 from among the specialty drug offerings. According to CuraScript, hepatitis C, multiple sclerosis,  
47 prostate cancer, and rheumatoid arthritis are just a few of the disease categories with multiple drug  
48 options that could be segmented in a drug formulary according to average wholesale price or

1 volume or other discounts that might be negotiated with the manufacturer (CuraScript, 2005). It is  
2 also anticipated that competition among specialty products may ultimately drive down costs of  
3 specialty drugs overall (Express Scripts, 2006).

4  
5 In addition, the administration requirements of a given specialty drug may be associated with its  
6 placement in a drug formulary. Specialty drugs have traditionally been administered by injection  
7 or infusion, which has added to their acquisition, storage, and administration costs. However, just  
8 as self-injectibles have arisen as an alternative to physician-administered drugs, so too are other  
9 forms of specialty drugs being introduced into the marketplace. Although drugs administered by  
10 infusion or injection still account for most drugs in the specialty pipeline (34% and 33%,  
11 respectively), 22% of drugs in the pipeline will be released in an oral form (Express Scripts, 2006).  
12 A small percentage of drugs (1%) are in development to be released under other forms, such as  
13 inhalants and nasal drops. (Administration forms have not yet been determined for the remaining  
14 drugs in the pipeline.) While not all specialty drugs are suitable for more traditional or less  
15 invasive forms of administration, the variety of administration methods represented in the pipeline  
16 indicates added potential for flexibility in formulary design.

#### 17 18 MEDICARE MODERNIZATION ACT OF 2003

19  
20 The Medicare Modernization Act of 2003 (MMA) introduced several changes to the way specialty  
21 pharmaceuticals are managed under the Medicare program. Prior to passage of the MMA,  
22 traditional Medicare covered drugs only if they were administered “incident to” a physician visit.  
23 Since many specialty pharmaceuticals have traditionally been administered by injection or infusion  
24 in a doctor’s office, Medicare patients often had access to these drugs through their Part B  
25 coverage. This is consistent with private plans historically covering specialty pharmaceuticals  
26 under the medical benefit. However, the creation of the Part D pharmaceutical benefit presents  
27 Medicare with the same administrative challenge private insurers are facing – namely deciding  
28 whether to process specialty drug costs through the patient’s medical (Part B) or pharmaceutical  
29 (Part D) benefit. Currently, providers and beneficiaries are being advised that drugs previously  
30 covered under Part B will continue to be provided under Part B, as long as the therapeutic use of  
31 the drug remains the same. That is, in some cases, the Part B/Part D classification depends not on  
32 the drug itself, but on the therapeutic indication. Some industry experts expect a shift from the use  
33 of physician administered drugs to ones that can be self-administered, so that they will be covered  
34 under Part D, rather than under Part B.

35  
36 In addition to creating a potential coverage alternative for some drugs eligible for coverage under  
37 Part B, Part D also offers coverage for many specialty pharmaceuticals that were previously not  
38 covered under Medicare. However, the majority of Part D plans are making a clear distinction in  
39 their formularies between specialty and other types of prescription drug therapies. The Centers for  
40 Medicare and Medicaid Services’ (CMS) guidance on formulary drugs lists for Part D plans  
41 includes a provision that allows plans to designate a single “specialty tier” to include “very high  
42 cost and unique items.” Recently, CMS clarified that “only Part D drugs with plan negotiated  
43 prices in excess of \$500 per month may be placed in the specialty tier.” Although so-called  
44 “specialty” drugs may be included in other formulary tiers, those that are placed in the specialty tier  
45 are exempt from the exceptions process, which allows beneficiaries to appeal cost sharing amounts.  
46 Such appeals are not permitted for any drugs placed in the specialty tier, thus patients are subject to  
47 the cost sharing arrangements required for that tier (generally 25% coinsurance).

1 Part D plans have rapidly adopted the use of a specialty tier. MedPAC reports that 60% of Part D  
2 plans have a tier designated for specialty drugs. In contrast, only about 4% of individuals enrolled  
3 in employer-sponsored plans are subject to a four-tier formulary (in which the fourth tier typically  
4 houses specialty drugs) (Kaiser Family Foundation and the Health Research and Educational Trust,  
5 2006). As noted in Council on Medical Service Report 2 (I-05), the trend toward distinct specialty  
6 tiers is likely to grow among private insurers, especially in light of its popularity among Part D  
7 insurers. It is important to note, however, that once patients reach their out-of-pocket spending  
8 limits in Medicare Part D, plans must cover specialty drugs according to the same formula by  
9 which other medically necessary drugs are covered (the greater of 5% coinsurance or between \$2  
10 and \$5 under the standard benefit). Thus, there is a cap on the amount of financial liability a  
11 beneficiary will incur as a result of specialty pharmaceutical use, regardless of where the drugs are  
12 placed on a formulary, or how initial cost sharing requirements are designed. Unlike Medicare,  
13 many private plans lack out-of-pocket maximums or catastrophic protections for pharmaceutical  
14 benefits, which raises significant concerns about specialty tiering spreading to private insurers.  
15

16 In addition to Part D, the MMA authorized CMS to offer participating physicians an alternative to  
17 the way they had previously obtained and been paid for drugs covered by Part B and administered  
18 in the physician's office. Prior to the MMA, physicians who frequently used specialty drugs to  
19 treat their patients had to purchase the drugs directly, and bill Medicare for the drug costs.  
20 Through the Competitive Acquisition Program (CAP), physicians are able to obtain drugs through  
21 vendors who contract with CMS. Currently a single vendor, BioScrip, serves the CAP program,  
22 and is responsible for maintaining drug inventories and billing Medicare. Physicians choosing to  
23 participate in the CAP program receive drugs as needed directly from BioScrip, and bill Medicare  
24 only for administering the drug.  
25

26 CAP essentially functions as a specialty pharmacy for physician-administered drugs in the  
27 Medicare program. The initial response to the CAP program has been one of caution. Although  
28 CMS had projected participation by approximately 2,000 physicians, current CAP enrollment is  
29 just over 300 (the enrollment period closed in June for program participation through the end of  
30 2006) (BioScrip Congressional Testimony, July 13, 2006). Physician reluctance to participate in  
31 the program stems from many concerns, including the inability to guarantee the integrity of drugs  
32 obtained through a CAP vendor; the lack of therapeutic flexibility associated with having to order  
33 drugs in advance and for specifically planned treatments; the likelihood that the regulatory  
34 prohibition on moving CAP drugs between offices will create barriers to delivering treatment in  
35 rural or other satellite locations; and the possibility that patients could be denied treatments if they  
36 fail to pay the coinsurance to the CAP vendor.  
37

### 38 RELEVANT AMA POLICY

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40 In general, AMA policy seeks to balance pharmaceutical costs and availability, with the emphasis  
41 on ensuring that patients have access to necessary medications as prescribed by their physicians.  
42 Specifically, Policy H-125.991[5] "encourages mechanisms, such as incentive-based formularies  
43 with tiered copayments, to allow greater choice and economic responsibility in drug selection, but  
44 urges managed care plans and other third-party payers to not excessively shift costs to patients so  
45 they cannot afford necessary drug therapies" (AMA Policy Database).  
46

47 Similarly, Policy H-110.997 "supports programs whose purpose is to contain the rising costs of  
48 prescription drugs, provided that...all patients must have access to all prescription drugs necessary

1 to treat their illnesses...” Although this statement is clear on the primacy of patient access, the  
2 policy also emphasizes that cost containment programs “should promote an environment that will  
3 give pharmaceutical manufacturers the incentive for research and development of new and  
4 innovative prescription drugs,” and “encourage expanded third party coverage of prescription  
5 pharmaceuticals and cost effective and medically necessary therapies.”  
6

7 Policies H-110.992 and H-110.995 focus on the pharmaceutical industry’s role in determining drug  
8 costs, and highlight the need to ensure costs do not have a negative impact on the availability and  
9 affordability of essential drugs.

10  
11 Policy H-285.965[10] urges health plans to make their medication formularies available to patients  
12 and physicians through a variety of media, including the Internet. In addition, Policy H-  
13 125.991[3.a.ii] states that a formulary system must openly provide detailed methods and criteria for  
14 the selection and objective evaluation of all available pharmaceuticals. Policy H-185.953, which  
15 was generated by Council on Medical Service Report 2 (I-05), calls for complete transparency of  
16 health care coverage policies related to specialty pharmaceuticals.

17  
18 Several recent policies address the role of pharmacy benefit managers in providing services to  
19 patients. Policies H-125.985 and D-125.997 address concerns related to the potential for  
20 interference in medical practice by PBMs, and encourage active involvement by physicians in  
21 reviewing treatment regimens for appropriateness. Policy D-125.996 calls for increased  
22 transparency of the business practices of PBMs, and advocates that PBMs provide information that  
23 allows health plans, employers and physicians to verify that the PBM is meeting its contractual  
24 obligations.

## 25 26 DISCUSSION

27  
28 The health care industry’s “solution” to balancing the cost of and access to specialty  
29 pharmaceuticals continues to evolve as insurers and industry experts continue to evaluate the effect  
30 of these drugs on health insurance costs. The information presented in Council on Medical Service  
31 Report 5 (I-05) remains relevant, and further information about the relationship between health  
32 plan treatment of specialty pharmaceuticals and patient access remains largely anecdotal.  
33

34 Nevertheless, the Council remains concerned that the need to manage the costs of specialty  
35 pharmaceuticals may overshadow the importance of ensuring that patients have appropriate access  
36 to effective therapies. For example, the transition of drug coverage from the medical benefit to the  
37 pharmacy benefit has the potential to increase access problems because patients will be required to  
38 pay pharmacies directly in order to obtain the necessary drugs. Individual pharmacies or pharmacy  
39 benefit managers may be more apt to deny therapies to patients who are unable to pay than would  
40 physicians, who often absorb the costs of patients who are unable to pay for necessary treatment.  
41

42 In addition, some physicians are concerned that the movement toward the use of PBMs and  
43 specialty pharmacies will significantly compromise treatment flexibility and the patient-physician  
44 relationship. The response to Medicare’s new CAP program for physician administered drugs  
45 underscores some significant physician concerns associated with the ability of physicians to retain  
46 flexibility in prescribing patient-specific therapies if they are restricted to a single pharmacy  
47 source. Similarly, there may be risks associated with entrusting the storage and preparation of

1 sensitive biologics and other drugs to third-party vendors. Physicians are reluctant to rely on  
2 commercial entities to ensure the safety of drugs with such unique storage requirements.

3  
4 Another concern with the use of PBMs is that their case management services may interfere with  
5 continuity of care and individual treatment regimens. Although PBM case management services  
6 are intended to help patients manage their medications, case managers often make  
7 recommendations based on only limited knowledge of the patient's medical history and condition.  
8 Especially among patients with chronic conditions for which specialty medications are typically  
9 indicated, it is critical that treatment decisions be made only after thorough and ongoing  
10 evaluations of an individual patient by his or her physician. Furthermore, the prior authorization  
11 and utilization review requirements imposed by many PBMs result in additional administrative  
12 burdens for physicians, and frequently lead to delayed patient care.

13  
14 The AMA is working with America's Health Insurance Plans and individual Medicare Part D plans  
15 to develop a set of "best practices" that can be used to ensure appropriate patient access to specialty  
16 drugs. The Council is hopeful that the health insurance industry's efforts to streamline and  
17 enhance data collection regarding the utilization patterns of specialty pharmaceuticals will help  
18 develop thoughtful approaches to specialty drug management that will preserve patient access.  
19 Consistent with Policies H-185.953 and D-125.996, the Council believes that transparency with  
20 regard to benefit design and coverage decisions affecting specialty pharmaceuticals will be critical  
21 to ensuring patient access.

22  
23 It is too soon to tell how health insurance treatment of specialty pharmaceuticals may affect patient  
24 access, but it is an issue that merits ongoing attention. This sentiment is shared by the editors of  
25 the journal *Health Affairs*, who made biotechnology drugs the focus of its September/October  
26 2006 issue. The journal's founding editor notes that "the policy issues surrounding biotechnology  
27 have not been prominent in our pages past, but they are taking on increasing importance as  
28 company pipelines surge and products are approved by the Food and Drug Administration (FDA).  
29 As a consequence, we are devoting this issue to papers that cover a range of topics central to the  
30 future of biotech, particularly those that apply to economics and insurance coverage." The issue's  
31 lead article, by economist James Robinson, "examines the evolving strategies of private health  
32 insurers as more biotech products come to market and as physicians and their patients demand  
33 access to them." Robinson's conclusion is similar to that reached by the Council, which is that it is  
34 too soon to determine if insurance company strategies will ultimately lead to an appropriate  
35 balance between access and affordability.

36  
37 Much of the information in this report, while not directly addressing patient access issues, is  
38 intended to provide greater insight into the factors that insurance companies find especially  
39 relevant to the utilization and monitoring of specialty pharmaceuticals. The Council believes that  
40 physicians, armed with this information, will be in a better position to advocate for their patients to  
41 help ensure access to necessary therapies. The Council will continue to monitor industry  
42 developments related to specialty pharmaceuticals, and looks forward to working with the Board of  
43 Trustees to ensure that AMA policy emphasizing patient access over cost control remains at the  
44 forefront of policy discussions.

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