

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 2 - I-05
(November 2005)

Subject: Health Insurance Coverage of Specialty
Pharmaceuticals

Presented by: Joseph P. Annis, MD, Chair

Referred to: Reference Committee K
(Eugenia Marcus, MD, Chair)

1 At the 2004 Interim Meeting, the House of Delegates adopted as amended Resolution 835, which
2 calls on the American Medical Association (AMA) to investigate the prevalence and impact in the
3 health insurance industry of tiered pharmaceutical benefits that significantly affect patients who
4 have diseases requiring expensive drugs for their treatment. The Board of Trustees referred
5 amended Resolution 835 (I-04) to the Council on Medical Service for study, with a report back to
6 the House at the 2005 Interim Meeting.

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8 The whereas clauses of the resolution single out “specialty pharmaceuticals” as the category of
9 drugs that could be adversely affected by tiered formulary structures. Accordingly, the following
10 report highlights the trends associated with the availability, cost, and utilization of specialty
11 pharmaceuticals; examines the use of tiered formularies; and explores possible alternatives for
12 managing the costs of specialty pharmaceuticals.

13
14 SPECIALTY PHARMACEUTICALS

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16 The term “specialty pharmaceutical” generally refers to specialized drugs that are used to treat one
17 of a variety of serious and chronic conditions such as cancer, multiple sclerosis, cystic fibrosis,
18 rheumatoid arthritis, and hemophilia. Examples include brand-name drugs such as *Enbrel* and
19 *Remicaid* for rheumatoid arthritis, and *Neupogen* and *Procrit*, supportive care therapies used during
20 cancer treatments. Although treatment with specialty pharmaceuticals can be extremely costly, in
21 many cases it represents a significant advancement over traditional therapeutic options, often
22 creating treatment options where none had existed previously. Many specialty drugs cause fewer
23 side effects, enhance quality of life, and prolong life expectancy for patients with chronic
24 conditions for whom other medical treatments had proven ineffective.

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26 The high cost of specialty pharmaceuticals can be attributed to many factors. Specialty
27 pharmaceuticals are often subject to specific handling and distribution requirements, and frequently
28 need to be administered by injection or infusion in a physician’s office. In addition to their unique
29 handling requirements, development costs for specialty pharmaceuticals are high, with researchers
30 relying on molecular and cellular technologies rather than on chemical processes to produce
31 effective therapies. The intrinsic value of the product itself also contributes to its high cost, since
32 many specialty pharmaceuticals have the potential to yield significant therapeutic benefits. Unlike
33 many other drugs, few therapeutic or generic alternatives exist for specialty pharmaceuticals. This
34 is the result of several factors, including the complexity of the development process, and the fact

1 that many drugs in this category are so new that their patents have not yet expired. In addition,
2 some products considered specialty pharmaceuticals are specifically “biologics” – a pharmaceutical
3 category for which an approval process for generic substitutes has not yet been established.
4

5 Specialty pharmaceuticals offer tremendous opportunities for successfully treating or managing an
6 increasing variety of complex and serious medical conditions. However, their extremely high cost
7 also has implications for overall health care expenditures. Although it is estimated that less than
8 5% of a typical health plan population currently utilizes specialty drugs, these drugs can account
9 for as much as 25% of a plan’s total costs. According to the pharmacy benefits manager Medco
10 Health Solutions, specialty drugs cost an average of \$18,000 per year, as compared to \$550 for
11 “traditional” medications (Managed Care Magazine, 2004).
12

13 Employers and insurers are beginning to focus particular attention on managing specialty drug
14 costs due to the consistent increase in spending on these products. According to the 2005 Medco
15 Drug Trend Report, spending on specialty drugs grew more than 20% in 2004, approximately twice
16 as much as the national average for drug spending. This growth reflects several factors, including
17 the introduction of new specialty pharmaceutical products; increased use of existing specialty drugs
18 for both original and new indications; and wider use of multiple drug therapy for some conditions.
19 Although these growth factors suggest exciting advancements in the treatment and management of
20 an increased variety of diseases, they also signal a trend of increasing costs for this type of
21 treatment, and stakeholders are being forced to consider how these costs can be absorbed by the
22 already strained health care system.
23

24 HEALTH INSURANCE TREATMENT OF SPECIALTY PHARMACEUTICALS

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26 Since the mere availability of many specialty pharmaceuticals is a new phenomenon, the question
27 of whether and how third-party payers will cover their costs is equally new. Few such drugs
28 existed five years ago, and now many more are being introduced each year. In 2003, the FDA
29 received more applications from biotechnology drug companies than from traditional drug
30 manufacturers (Medco Drug Trends Report, 2004).
31

32 Because many specialty pharmaceuticals require administration by injection or infusion in a
33 physician’s office, they have frequently been covered as a medical benefit, rather than as part of a
34 pharmaceutical benefit. However, as the availability and use of these types of drugs becomes more
35 prevalent, insurers are seeking ways to track and control costs more aggressively. As a result,
36 some insurers are designing plans that manage specialty pharmaceutical costs through the
37 pharmaceutical benefit, which shifts more costs directly to the patient, and allows insurers to use
38 utilization management and cost-sharing mechanisms to more directly monitor and influence
39 specialty pharmaceutical usage.
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41 TIERED PHARMACEUTICAL BENEFITS

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43 The vast majority (88%) of individuals participating in employer-sponsored health plans receive
44 prescription drugs through some kind of tiered formulary. Tiered formularies, which are generally
45 supported by the AMA (Policy H-125.991[5], AMA Policy Database), have been adopted by third-
46 party payers as a way of controlling drug costs, while also preserving choice for patients and
47 physicians by ensuring some level of coverage for most drugs. The most common formulary
48 design has three tiers: generics, “preferred” brand name drugs, and “non-preferred” brand name

1 drugs. In general, brand name drugs without lower cost generic substitutes are covered in the
2 middle tier, along with drugs for which the insurer has negotiated significant discounts. Results
3 from the 2004 Annual Survey of Employer-Sponsored Health Benefits, conducted by the Kaiser
4 Family Foundation and Health Research and Educational Trust (KFF/HRET), reveal that 65% of
5 covered workers are subject to a three-tier cost sharing formula.

6
7 Tiered formularies may utilize co-payments (a fixed dollar amount per prescription), co-insurance
8 (patients pay a percentage of the total drug cost), or a combination of both to promote cost sharing.
9 According to the KFF/HRET survey, use of a co-payment is the most frequent type of cost sharing,
10 with average co-payments in a three-tier design of \$10 for generics, \$21 for preferred drugs, and
11 \$33 for non-preferred drugs. Co-insurance rates average 20%, 26% and 31% for the same
12 categories.

13
14 As noted in Resolution 835 (I-04), some health insurers are developing new plan designs to address
15 the increasing demand for high-cost specialty pharmaceuticals. A growing number of plans are
16 introducing a formulary tier reserved for expensive specialty or biotech drugs. In many cases, this
17 represents a formulary's fourth tier, although formulary tiers can be split in a variety of ways. The
18 2004 KFF/HRET Survey was the first in which questions regarding the use of formulary structures
19 with four tiers were included. According to the survey, 3% of workers were enrolled in plans with
20 four levels of pharmaceutical coverage. Although this is a relatively small number, industry
21 experts have noticed an increase in the number of employers interested in designing plans to
22 manage the increased use of specialty drugs.

23 24 VARIATIONS ON TIERED PHARMACEUTICAL BENEFITS

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26 Most tiered formularies are structured to encourage the use of generic or otherwise lower cost
27 brand name drugs over more expensive brand-name alternatives. Designing a formulary structure
28 that reasonably incorporates specialty pharmaceuticals is challenging, because in many cases there
29 are few or no alternative therapies, and often a drug may be life-saving for the patient. Many
30 insurance companies are exploring more nuanced variations of tiered formularies to accommodate
31 these unique circumstances while still allowing for a certain level of cost control.

32
33 "Value-based" tiering structures use factors other than an individual drug's acquisition costs to
34 determine coverage levels. For example, some insurance companies have considered basing cost-
35 sharing levels on the severity of the condition being treated, rather than the treatment itself. Other
36 plan designs attempt to quantify the potential for cost savings (in the form of precluded the need for
37 future medical treatment) associated with utilizing a certain drug. Drugs that could be expected to
38 yield a decrease in future medical expenses would be placed in a lower cost-sharing tier. A third
39 variation on the value-based model could include weighing medical condition, predicted usage
40 (i.e., symptomatic relief; ongoing/maintenance; limited duration) and predicted health outcomes to
41 determine the overall value received from the treatment. In this scenario, highest co-payment
42 levels might be assigned for conditions that are relatively minor, and for which the drug is not
43 expected to have a significant impact on long-term patient health or medical costs. Conversely,
44 lowest co-payments would be assigned for drugs prescribed to patients with acute conditions from
45 which full recovery and significant cost savings could be expected from full compliance with the
46 drug regimen.

1 Some plans also utilize a hybrid co-payment/co-insurance structure to manage costs of high cost
2 pharmaceuticals. Plans that use a co-payment structure for some drug tiers may shift to some level
3 of co-insurance (generally between 20% and 30%) for specialty pharmaceuticals. Because patients
4 pay a percentage of the drug cost under a co-insurance structure, they will end up incurring greater
5 out-of-pocket costs than under a co-payment structure.

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7 AMA POLICY
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9 In general, AMA policy seeks to balance pharmaceutical costs and availability, with the emphasis
10 on ensuring that patients have access to necessary medications prescribed by their physicians.
11 Specifically, Policy H-125.991[5] “encourages mechanisms, such as incentive-based formularies
12 with tiered copays, to allow greater choice and economic responsibility in drug selection, but urges
13 managed care plans and other third-party payers to not excessively shift costs to patients so they
14 cannot afford necessary drug therapies.”

15
16 Similarly, Policy H-110.997 “supports programs whose purpose is to contain the rising costs of
17 prescription drugs, provided that...all patients must have access to all prescription drugs necessary
18 to treat their illnesses...” Although this statement is clear on the primacy of patient access, the
19 policy also emphasizes that cost containment programs “should promote an environment that will
20 give pharmaceutical manufacturers the incentive for research and development of new and
21 innovative prescription drugs,” and “encourage expanded third-party coverage of prescription
22 pharmaceuticals and cost effective and medically necessary therapies.”

23
24 Policies H-110.992 and H-110.995 focus on the pharmaceutical industry’s role in determining drug
25 costs, and highlight the need to ensure costs do not have a negative impact on the availability and
26 affordability of essential drugs.

27
28 AMA Policy H-285.965[10] urges health plans to make their medication formularies available to
29 patients and physicians through a variety of media, including the Internet. Additionally, Policy
30 H-125.991[3.a.ii] states that a formulary system must openly provide detailed methods and criteria
31 for the selection and objective evaluation of all available pharmaceuticals.

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33 DISCUSSION
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35 Since specialty pharmaceuticals are an emerging therapy, it may be useful to consider them as the
36 next step in the evolution of prescription drug coverage. The Council has previously considered
37 the issue of cost sharing obligations for drugs approved under a medical exceptions process
38 (Council on Medical Service Report 6, A-03). In that report, the Council recommended that
39 individuals should not be financially penalized for using a medical exceptions process, and that, if
40 approved, the co-payment for prescription drugs covered under the exceptions process should not
41 exceed the highest existing co-payment tier. The report states “the Council believes that incurring
42 a significant financial penalty for utilizing the exceptions process is tantamount to having no
43 exceptions process at all.” The resulting policy, H-185.961, states that third-party payers should
44 not establish a higher cost-sharing requirement exclusively for prescription drugs approved for
45 coverage under a medical exceptions process. When Council Report 6 (A-03) was written, it is
46 likely that many specialty drugs were not included in payer formularies, and were therefore open to
47 coverage only through the medical exceptions process.

1 In anticipation of the availability of specialty pharmaceuticals to treat an increasing number of
2 patients for an expanding array of medical conditions, insurers are relying heavily on the traditional
3 tiered pharmaceutical benefit framework as a template to help control the potentially explosive
4 costs of these drugs. One option has been to carve out a separate tier for specialty pharmaceuticals,
5 and to require higher levels of patient cost-sharing to cover their uniquely high costs.

6
7 Other plans are exploring more nuanced “value-based” tiering structures, which could offer more
8 flexible coverage based on an evaluation of not only the cost of the drug, but also its indication and
9 the health outcomes associated with its use. While the Council on Medical Service finds this
10 sophisticated approach to balancing cost with patient needs and anticipated outcomes interesting,
11 there is some concern that it would be extremely difficult to develop a fair and objective formulary
12 based on therapeutic need or medical condition. The Council believes that it is critical that
13 insurance companies be able to clearly articulate how co-payment levels are assessed for specialty
14 pharmaceuticals.

15
16 The author of Resolution 835 (I-04) provided comments that indicated that some insurers fail to
17 disclose how specialty pharmaceuticals are incorporated into their formulary structures. Because
18 relatively few patients utilize specialty drugs (and healthy individuals cannot imagine ever needing
19 to use them) their presence (or absence) in a tiered formulary is easily overlooked or considered
20 secondary to the availability of other, more common drug therapies. In some instances, insurers
21 highlight the use of a separate formulary tier to manage the cost of “lifestyle” drugs (e.g., those
22 used for cosmetic purposes or to enhance sexual function), while failing to note that very
23 expensive, but vital, biotech drugs are included in the same tier. The Council believes that this lack
24 of transparency in coverage levels makes it difficult to thoroughly evaluate the adequacy of a drug
25 benefit, and makes it equally difficult for patients and physicians to anticipate treatment costs.

26
27 The Council is also concerned that patients may effectively lose access to critical drug therapies if
28 the cost sharing requirements become too great. Council on Scientific Affairs Report 2 (A-04)
29 provided an in-depth review of tiered formularies and their outcomes on patient care. There is
30 limited information about the impact of incentive-based tiered formularies on patient outcomes,
31 and no research has been done related specifically to the availability of coverage for specialty
32 pharmaceuticals. However, Council on Scientific Affairs Report 2 (A-04) concluded that there is
33 some evidence that tiered formularies could lead to decreased utilization of necessary drugs, which
34 could produce a negative impact on patients.

35
36 The Council is sensitive to the need to ensure patient access while effectively managing and
37 controlling health care costs. Specialty pharmaceuticals, with their high costs and potential for
38 improving the lives of patients, offer a clear example of the difficulties associated with maintaining
39 this balance. Policy H-125.991[5] clearly states that insurers should not excessively shift costs to
40 patients so as to make drug therapies unaffordable. The Council believes that this policy should
41 serve as a guide as specialty pharmaceuticals continue to expand their presence in the health care
42 landscape.

43
44 Finally, the Council believes that the lifetime benefits of any health insurance policy should be
45 sufficient to guarantee a reasonable level of coverage throughout the policy holder’s lifetime.
46 Patients with chronic illnesses are at risk for exhausting their lifetime benefits if treatment costs are
47 high, regardless of the level of cost sharing assigned to the insured. The Council is encouraged by
48 recent data that indicate that nearly half (49%) of employer-sponsored plans have no lifetime

1 benefit limits, and an additional 25% have a limit of \$2,000,000 or more (Kaiser/HRET, 2004).
2 However, more than a quarter of employer sponsored plans still limit lifetime benefits to less than
3 \$2,000,000. As the use of expensive specialty pharmaceuticals becomes more prevalent,
4 individuals insured by plans with lower lifetime benefit caps will be at risk for exhausting their
5 benefits during the course of their treatment. Accordingly, the Council encourages all plans to
6 increase or eliminate the lifetime benefit maximums to help ensure that patients with chronic
7 conditions are able to rely on their insurance policies to share some portion of the cost.
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9 RECOMMENDATIONS

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11 The Council on Medical Service recommends that the following be adopted and that the remainder
12 of the report be filed:
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- 14 1. That the American Medical Association (AMA) reaffirm Policy H-125.991[5], which “
15 encourages mechanisms, such as incentive-based formularies with tiered co-pays, to allow
16 greater choice and economic responsibility in drug selection, but urges managed care plans and
17 other third-party payers to not excessively shift costs to patients so they cannot afford
18 necessary drug therapies.” (Reaffirm HOD Policy)
19
- 20 2. That the AMA support complete transparency of health care coverage policies related to
21 specialty pharmaceuticals, including co-payment or co-insurance levels and how these levels
22 are determined. (New HOD Policy)
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- 24 3. That it be the policy of the AMA that employers and health insurers should eliminate the
25 lifetime maximums on health insurance benefits. (New HOD Policy)
26
- 27 4. That the AMA continue to monitor health plan treatment of specialty pharmaceuticals to ensure
28 patient access to needed pharmaceuticals, and report back to the House of Delegates at the
29 2006 Interim Meeting. (Directive to Take Action)

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

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