INFORMATION BRIEF
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Medical Assistance: Drug Coverage and Reimbursement

This information brief provides an overview of drug coverage and reimbursement under Medical Assistance (MA), Minnesota's Medicaid program. Many of the provisions described here also apply to the MinnesotaCare program.

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Drug Coverage

Under federal law, drug coverage is an optional Medicaid benefit. Minnesota, and all other states, have chosen to cover drugs under their Medicaid programs.

Fee-for-service

Minnesota's MA program covers a broad range of prescription and over-the-counter (nonprescription) drugs under fee-for-service. This broad coverage in part reflects federal Medicaid requirements that states cover under their formulary[1] all drugs offered by manufacturers that have entered into a Medicaid rebate agreement with the federal Centers for Medicare and Medicaid Services or CMS (see below for a discussion of rebates).

Federal law allows states to exclude specified categories of drugs from coverage under their Medicaid programs (Social Security Act § 1927, 42 USC § 1396r-8). Minnesota has chosen to cover some of these drug categories, including drugs for weight gain, certain products to treat cough and colds, drugs to promote smoking cessation, some prescription vitamins and mineral products, some over-the-counter drugs, barbiturates, and benzodiazepines.[2]

Some of the major categories of drugs for which Minnesota's MA program excludes coverage are the following:

1. Most drugs used for weight loss
2. Fertility drugs when specifically used to enhance fertility
3. Drugs when used for cosmetic purposes or hair growth
4. Over-the-counter drugs, unless authorized in law or by the commissioner
5. Drugs that require, as a condition of sale, that associated tests or monitoring be purchased exclusively from the manufacturer
6. Drugs when used for the treatment of impotence or erectile dysfunction
7. Herbal or homeopathic products
8. Nutritional supplements, except as specifically allowed
9. Drugs determined to be less than effective by the Food and Drug Administration and drugs identified as identical, related, or similar to those drugs
10. Drugs that do not provide a significant therapeutic advantage over drugs included in the formulary, as long as a written explanation of the reason is provided to the public

[1] A formulary is a list of preferred drugs that is typically used to limit the number of drugs within a therapeutic class for purposes of drug purchasing, dispensing, or reimbursement. See Glossary of Pharmacy-Related Terms, Health Resources and Services Administration, U.S. Department of Health and Human Services, accessed at http://www.hrsa.gov/opa/glossary.htm.

[2] Beginning January 1, 2014, the federal Affordable Care Act will require all state Medicaid programs to cover barbiturates, benzodiazepines, and smoking cessation products.

11. Drugs that are made by manufacturers that do not have a rebate agreement with CMS

MA covers the following over-the-counter medications under fee-for-service, when they are prescribed by a licensed practitioner or a licensed pharmacist who meets standards established by the Department of Human Services (DHS):

- Antacids, acetaminophen, family planning products, aspirin, insulin, products for the treatment of lice, and certain vitamins
- Medications identified by the commissioner, after consultation with the Formulary Committee,[3] as necessary, appropriate, and cost-effective

Drug coverage for MinnesotaCare under fee-for-service is the same as that under MA fee-for service. (The vast majority of MinnesotaCare enrollees are covered under managed care.)

Managed Care

Managed care plans serving MA enrollees are required to cover prescription and over-the-counter drugs that are covered under the MA fee-for-service drug formulary or are the therapeutic equivalent to MA formulary drugs. The requirements described in this section also apply to managed care plans serving MinnesotaCare enrollees.

If the managed care plan's drug formulary or policies are more restrictive than the MA fee-for-service drug formulary or policies, the plan must cover, at its own cost, any drug necessary for an enrollee for whom the state intervenes, following a state review by a pharmacist and physician. If the state intervenes, it must require the managed care plan to implement a corrective action plan.

Managed care plans are also required to submit to DHS, upon request, a copy of their drug formularies. If DHS finds that a plan's formulary does not contain a therapeutic equivalent for a class of drugs, the agency requires the managed care plan to submit a corrective action plan.

Managed care plans must also comply with Minnesota Statutes, section 62Q.527, which requires health plans that provide prescription drug coverage to cover antipsychotic drugs prescribed to treat emotional disturbance or mental illness whether or not the drug is in the plan formulary, if specified conditions are met.

Coverage for Dual Eligibles

Persons who are eligible for both MA and Medicare (referred to as "dual eligibles") receive coverage for prescription drugs through the Medicare Part D prescription drug benefit. The only coverage provided under MA for dual eligibles is for those classes of drugs for which coverage

[3] The Formulary Committee, established by DHS in accordance with Minnesota Statutes, section 256B.0625, subdivision 13c, consists of four physicians, at least three pharmacists, one consumer representative, and other health care professionals.

under the Medicare prescription drug coverage is prohibited by law.[4] The MA program will not cover a specific prescription drug for a recipient solely because it is not covered under the formulary of the recipient's Medicare drug plan.

Prior Authorization

MA requires prior authorization before certain brand-name and generic drugs are eligible for payment under fee-for-service. The DHS Formulary Committee may recommend to the commissioner prior authorization for specific drugs. The commissioner may also request the committee to review whether prior authorization should be required for a specific drug.

Prior authorization is prohibited for certain antihemophilic factor drugs and certain atypical antipsychotic drugs,[5] under specified conditions. In addition, prior authorization must be granted for 60 days for brand-name drugs prescribed for the treatment of mental illness within 60 days of a generically equivalent drug becoming available.

Generic Substitution

MA coverage of prescription drugs under both fee-for-service and managed care is generally subject to Minnesota Statutes, section 151.21. This provision requires pharmacists to substitute, when appropriate in the pharmacist's professional judgment, a less expensive generic drug in place of a brand-name drug, unless the purchaser objects or the prescriber has written on the prescription "dispense as written" or "D.A.W.," or conveyed this intent by electronic transmission or orally. MA normally requires prior authorization for brand-name drugs when there is a generic drug available, even if the prescriber specifies "dispense as written" for the brand-name drug. Prior authorization of a brand-name drug may not be required if the net cost[6] of the brand name is less than the net cost of the generic.

[4] Some of the drug classes excluded under Medicare Part D are over-the-counter drugs, prescription vitamins and minerals, barbiturates, and benzodiazepines. The Affordable Care Act will require Medicare Part D coverage of barbiturates and benzodiazepines, beginning January 1, 2013. The Medicare program requires states to reimburse the federal government for a portion of the cost of providing dual eligibles with drug coverage (initially 90 percent and declining over time to 75 percent of the estimated cost to the state Medicaid program of providing prescription drug coverage). This is referred to as the "clawback."

[5] These drugs are not defined specifically in law but generally refer to "second generation" antipsychotic drugs that tend to have fewer side effects than older antipsychotic drugs.

[6] Net cost is equal to the reimbursement to the provider less all drug rebates.

Drug Reimbursement

Fee-for-service

Under the MA fee-for-service program, pharmacies are reimbursed for most drugs at the lower of: (1) wholesale acquisition cost (WAC)[7] plus 2 percent or 4 percent (depending upon pharmacy type) plus a fixed dispensing fee; (2) the maximum allowable cost set by the federal government or DHS plus a fixed dispensing fee; or (3) the pharmacy's usual and customary price charged to the public. The fixed dispensing fee in most cases is $3.65 per prescription; higher dispensing fees are allowed for intravenous solutions compounded by a pharmacist, cancer chemotherapy products, and total parenteral nutritional products (see Minn. Stat. § 256B.0625, subd. 13e).

1. *WAC formula.* The MA program reimburses pharmacies at WAC plus 4 percent (for independently owned pharmacies located in a designated rural area) or WAC plus 2 percent (for all other pharmacies). WAC is the manufacturer's list price charged to wholesalers and other direct purchasers, not including discounts, rebates, and price reductions. A pharmacy is "independently owned" if it is one of four or fewer pharmacies under the same ownership nationally. A "designated rural area" is an area classified as a small rural area or isolated rural area under the Rural Urban Commuting Area system developed for the federal Health Resources and Services Administration.

2. *Maximum allowable cost.* MA reimbursement to pharmacies for multiple-source drugs (drugs for which at least one generic exists) may be subject to a maximum allowable cost (MAC). The purpose of a MAC price is to set the reimbursement rate closer to the actual acquisition cost of the generic drug. Federal law requires CMS to set a MAC (referred to as a federal upper limit or FUL) for certain multiple-source drugs. Each state's Medicaid program must meet an aggregate FUL for all drugs for which CMS has set a FUL. States can also set state MACs for multiple-source drugs that are lower than any FUL and for drugs for which CMS has not set a FUL. Minnesota has chosen to set state MACs for a large number of multiple-source drugs.

3. *Usual and customary price.* MA reimburses pharmacies at the usual and customary price charged to the public, if this is lower than the payment rate under the WAC formula or the MAC price. This provision allows the MA program to reimburse large chain pharmacies for generic drugs provided to MA recipients at their discounted price for the general public (e.g., $4.00 per prescription).

   In addition, the MA program has negotiated payment rates lower than those described above for specialty pharmacy products, defined as those used by a small number of recipients or by recipients with complex and chronic diseases requiring expensive and challenging drug regimens (see Minn. Stat. § 256B.0625, subd. 13e, para. (e)).

[7] Prior to July 1, 2011, MA reimbursement to pharmacies was expressed in law as a percentage reduction off the average wholesale price (AWP), generally defined as a drug wholesaler's list price to pharmacies. A 2009 federal district court class action settlement in part resulted in two drug price publishing companies voluntarily agreeing to stop publishing AWP price data. This required Minnesota and other states to modify their Medicaid drug reimbursement formulas by incorporating a measure of drug costs that was not based on AWP.

Fee-for-service reimbursement under MinnesotaCare follows the MA fee-for-service payment methodology. Nearly all MinnesotaCare enrollees receive drug coverage and other MA covered services through managed care.

Managed Care

The MA and MinnesotaCare programs do not specify or regulate the payment rates at which managed care plans reimburse pharmacies for prescription drugs.

Pharmacy Purchases of Drugs

The MA and MinnesotaCare programs do not regulate the prices at which pharmacies purchase drugs from wholesalers, manufacturers, and other entities. These prices are instead left to negotiation and private market forces.

Recipient Cost-sharing

MA recipients are subject to copayments of $3 per brand-name prescription and $1 per generic prescription, subject to a $12 per-month limit. Antipsychotic drugs are exempt from copayments when used for the treatment of mental illness.

Children and pregnant women are exempt from these copayments. Total monthly copayments under MA for persons with incomes not exceeding 100 percent of the federal poverty guidelines (FPG) are limited to 5 percent of family income.

Pharmacists are responsible for collecting the copayment from enrollees. MA reimbursement to a provider is reduced by the amount of the copayment; however, this reduction does not apply when a recipient has reached the monthly prescription drug copayment limit or the overall 5 percent copayment maximum. Providers cannot deny services to enrollees who are unable to pay the copayment.[8]

MinnesotaCare enrollees are subject to a copayment of $3 per prescription, with no monthly maximum. This copayment does not apply to pregnant women and children.

[8] Minnesota Statutes, section 256B.0631, subdivision 4, allowed providers who routinely refused services to individuals with uncollected debt to include uncollected copayments as bad debt and deny services to enrollees. The Ramsey County District Court in *Dahl et. al. v. Goodno*, court file number C9-04-7537, ruled that this provision was preempted by federal law. The provision was repealed January 1, 2009.

Drug Rebates

The Basic Federal Rebate

The federal Omnibus Budget Reconciliation Act (OBRA) of 1990 requires drug manufacturers to provide rebates to state Medicaid programs in order to have their drugs covered under Medicaid fee-for-service. In general, the formula used to calculate rebates is intended to provide Medicaid with the "best" (lowest) price[9] at which a manufacturer sells the drug. In return for manufacturers providing the best price, state Medicaid programs are required to cover under fee-for-service all drugs offered by the manufacturer (with the exception of those drug categories a state is allowed to exclude from coverage).

The basic federal rebate formula differs based upon drug category. For noninnovator multiple-source (generic) drugs, the rebate is 13 percent of the average manufacturer price (AMP). The AMP is a measure of the price charged by manufacturers to wholesalers for a drug. The AMP was created in federal law for the purpose of calculating rebates. For single-source and innovator multiple-source (brand-name) drugs,[10] the rebate is the greater of 23.1 percent of AMP or the AMP minus the best price. An additional rebate is required for this latter category of drugs if the price of the drug product increases faster than inflation as measured by the CPI.

The federal rebate requirement generally applies to drugs provided in an outpatient setting, on a fee-for-service basis and, since March 23, 2010, to drugs provided through managed care plans. The federal rebate requirement does not apply to drugs provided in hospitals, or in outpatient settings under which drug claims are not billed separately.

Rebates are paid by drug manufacturers to each state on a quarterly basis, based upon utilization data provided by each state Medicaid program.[11]

Supplemental Rebates

Some states, including Minnesota, have negotiated supplemental rebates beyond the basic rebate required by federal law. Minnesota law authorizes DHS to enter into supplemental rebate agreements with manufacturers who want their drug to be placed on a preferred drug list. Drugs not on the preferred drug list may be subject to prior authorization. DHS maintains the preferred drug list on its website.

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[9] The best price calculation excludes drugs sold to the Indian Health Service, the Department of Veterans Affairs, the Department of Defense, and other specified entities.

[10] A single-source drug is one for which no generic exists. An innovator multiple-source drug is one that was originally marketed under an original new drug application approved by the Food and Drug Administration, for which generic products do exist.

[11] The rebate percentages specified above reflect increases, authorized by the federal Affordable Care Act (ACA), that took effect January 1, 2010. Prior to this date, the rebate percentages were 11 percent of AMP for generic drugs and 15.1 percent of AMP for brand-name drugs. The ACA provides that the federal government retains all savings resulting from the increases in the rebate percentages.

Acronyms and Definitions Related to Prescription Drug Reimbursement

AMP: average manufacturer price; the average price paid by wholesalers to a manufacturer for drugs distributed to retail pharmacies. AMP is net of discounts provided for the payment of invoices within a specified period of time (prompt-pay discounts) and was a benchmark created by the U.S. Congress in 1990 to calculate Medicaid rebates.

FUL: federal upper limit; the price calculated and published by the Centers for Medicare and Medicaid Services as the maximum amount that a state Medicaid program can pay for a multiple-source (generic) drug.

MAC: maximum allowable cost; the upper limit on payment set by state Medicaid programs (or other payers) for equivalent drugs available from multiple manufacturers.

WAC: wholesale acquisition cost; defined in Minnesota Statutes, section 256B.0625, subdivision 13e, paragraph (a) as "the manufacturer's list price for a drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which information is available, as reported in wholesale price guides or other publications of drug or biological pricing data."

Sources: The definitions above are from: "AMCP Guide to Pharmaceutical Payment Methods," 2009 Update (Version 2.0), Glossary, Academy of Managed Care Pharmacy; and Glossary of Pharmacy-Related Terms, Health Resources and Services Administration, U.S. Department of Health and Human Services, accessed at http://www.hrsa.gov/opa/glossary.htm. In some cases, definitions are abbreviated or slightly modified.

For more information about medical assistance, visit the health and human services area of our website, www.house.mn/hrd/hrd.htm.