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Report to Congressional Committees

December 2005

MEDICARE AND MEDICAID COVERAGE

Therapies and Supplies for Inflammatory Bowel Disease

GAO-06-63

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Highlights

Highlights of GAO-06-63, a report to congressional committees

Why GAO Did This Study

Inflammatory bowel disease (IBD) affects an estimated one million Americans. IBD patients often have difficulty digesting food. As a result, they may require parenteral nutrition (intravenous feeding) or enteral nutrition (tube feeding), medically necessary food products to supplement their diets, and medications. In addition, some IBD patients must care for their ostomies—surgically created openings for the discharge of digested food.

IBD advocates have recently expressed concerns regarding the ability of IBD patients to obtain the health care they need. The Research Review Act of 2004 directed GAO to study the Medicare and Medicaid coverage standards for individuals with IBD, in both home health and outpatient delivery settings. GAO (1) identified the Medicare and Medicaid coverage standards for five key therapies used for the treatment of IBD and (2) determined what specific supplies used in these therapies Medicare and Medicaid programs will pay for. In this work, GAO examined Medicare's national and local coverage policies and conducted a survey of Medicaid programs in the 50 states and the District of Columbia.

www.gao.gov/cgi-bin/getrpt?GAO-06-63.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Leslie G. Aronovitz, at (312) 220-7600 or aronovitzl@gao.gov.

What GAO Found

Medicare generally provides coverage for parenteral and enteral nutrition and ostomy supplies in both home health and outpatient delivery settings. However, specific standards regarding medical conditions and appropriate documentation must be met for parenteral and enteral nutrition to be covered. Medicare has one coverage standard governing the provision of ostomy supplies—that beneficiaries receiving these items have had an ostomy. Medicare does not cover medically necessary food products and generally does not cover self-administered drugs, which include most drugs taken by IBD patients. However, medically necessary drugs, including those that are self-administered, will be covered by Medicare's voluntary prescription drug benefit, which becomes effective in January 2006. State Medicaid programs reported covering, at least partially, each of the five therapies. The survey indicated that most states' Medicaid coverage standards are generally comparable to Medicare's coverage for parenteral and enteral nutrition and ostomy care.

State Medicaid Programs That Reported Coverage of Five IBD Therapies for Adults and Children

	Parenteral nutrition	Enteral nutrition	Ostomy care	Medically necessary food products	Drugs[a]
Adults and children	50	49	51	40	50
Adults only	0	0	0	0	1
Children only	1	1	0	6	0
Not covered	0	1	0	5	0
Total	**51**	**51**	**51**	**51**	**51**

Source: GAO survey of state Medicaid programs.

Note: For purposes of this report, the District of Columbia is considered a state.

[a]For this analysis, GAO is defining states' coverage of drugs to treat IBD as states' coverage of at least one of the brand name drugs or generic drugs listed in GAO's survey.

Once Medicare coverage standards are met, the program will generally cover all medically necessary supplies associated with parenteral and enteral nutrition and ostomy care. The survey of state Medicaid programs showed variation in the specific supplies that states will provide. While many states pay for most supplies associated with parenteral and enteral nutrition, the specific ostomy supplies states cover vary. Most states—46—reported covering at least some medically necessary food products. GAO also found that states generally cover the drugs listed in the survey.

CMS said that GAO correctly described its Medicare coverage policies and suggested that we clarify our description of Medicare's coverage policy for prescription drugs that are not self-administered. It also said that it will continue to consider access issues for Medicare and Medicaid IBD patients.

Contents

Tables

Figure

Abbreviations

BIPA	Benefits Improvement and Protection Act of 2000
CMS	Centers for Medicare & Medicaid Services
DMERC	Durable Medical Equipment Regional Carrier
FDA	Food and Drug Administration
HCPCS	Health Care Common Procedure Coding System
HHS	Department of Health and Human Services
IBD	inflammatory bowel disease
LCD	local coverage determination
LMRP	local medical review policies
NCD	national coverage determination

GAO
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United States Government Accountability Office
Washington, DC 20548

December 15, 2005

The Honorable Charles E. Grassley
Chairman
The Honorable Max Baucus
Ranking Minority Member
Committee on Finance
United States Senate

The Honorable Joe Barton
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

The Honorable William M. Thomas
Chairman
The Honorable Charles B. Rangell
Ranking Minority Member
Committee on Ways and Means
House of Representatives

Inflammatory bowel disease (IBD) refers to two chronic autoimmune diseases of the intestinal tract—Crohn's disease and ulcerative colitis. These diseases may result in abdominal pain, weight loss, fever, rectal bleeding, and diarrhea, and are associated with a decreased quality of life. IBD generally involves periods of active inflammation alternating with periods of remission.

The estimated one million Americans with IBD[1]—10 percent of whom are children—have difficulty digesting food and may require different treatments, depending on the specific nature of their condition. As a result, some IBD patients may periodically require parenteral nutrition—the provision of nutrients intravenously. Others may receive enteral nutrition, which is delivered through a feeding tube inserted into their

[1]According to the Crohn's Disease and Colitis Foundation of America, the number is evenly split between the two diseases.

noses or stomachs. Some IBD patients may require nutrition in the form of medically necessary food products, such as formulas that are more easily digested than normal foods.[2] IBD patients may also require medication, and some may have ostomies—surgically created openings in their abdominal wall for the discharge of digested food—and therefore depend on a pouching system to collect, contain, and manage disposal of solid body waste.

A number of IBD patients depend on Medicare and Medicaid,[3] the nation's largest health insurance programs, for coverage of their treatment. Medicare serves approximately 41 million elderly and certain disabled beneficiaries and is administered by the Centers for Medicare & Medicaid Services (CMS), an agency within the Department of Health and Human Services (HHS). Based on the Social Security Act,[4] CMS, and the claims administration contractors that assist it in administering the Medicare program, determine whether specific medical procedures, devices, and services should be covered. Medicaid is a federal-state program that finances health care coverage for approximately 54 million low income individuals, about half of whom are children. Under CMS's oversight, each state administers its own Medicaid program. Within broad coverage requirements set by law and CMS, states have discretion to develop specific coverage policies for their Medicaid programs. In fiscal year 2004, Medicare paid about $298 billion for services and supplies provided to beneficiaries while Medicaid programs paid close to $272 billion.[5]

Over the past few years, IBD advocates have tried to raise awareness about IBD and the challenges IBD patients face, including concerns about obtaining the health care that they need to manage their disease. The Research Review Act of 2004 contains several provisions related to IBD, including a mandate that we conduct a study on the Medicare and Medicaid coverage standards for IBD patients.[6] The act required us to

[2]Enteral nutrition formula may be also consumed orally, depending on the patient's condition, instead of via tube-feeding. In this report, we consider enteral nutrition formulas that are consumed orally as medically necessary food products.

[3]The number of Medicare and Medicaid beneficiaries who are IBD patients is not known.

[4]Medicare was established in 1965 in Title XVIII of the Social Security Act and is codified as amended at 42 U.S.C. §§ 1395-1395hhh.

[5]Medicaid payment includes federal and state contributions.

[6]Pub. L. No. 108-427, § 4, 118 Stat. 2430, 2431.

focus on five specific therapies—in both home health and outpatient delivery settings[7]—parenteral nutrition, enteral nutrition formula, ostomy care,[8] medically necessary food products, and drugs approved by the Food and Drug Administration (FDA) for Crohn's disease and ulcerative colitis.[9] In this report, we (1) identify the Medicare and Medicaid coverage standards for these five therapies, and (2) determine which specific supplies used in these therapies Medicare and Medicaid programs will pay for in home health and outpatient delivery settings.

To determine Medicare's coverage standards for the five therapies, we obtained and reviewed relevant Medicare laws, regulations, national coverage policies, and manuals to identify pertinent material. We also interviewed CMS officials and the medical directors of the Durable Medical Equipment Regional Carriers (DMERC)—the four claims administration contractors involved in making local coverage decisions for applicable therapies in our study. In addition, we discussed and obtained documentation regarding specific supplies used in the five therapies that Medicare would pay for in both home health and outpatient delivery settings.

To obtain information on Medicaid's coverage of the five therapies, we developed a survey that we sent to Medicaid offices in all 50 states and the District of Columbia[10] and asked them to identify applicable coverage standards. The survey asked state officials to identify specific supplies their Medicaid program would pay for. It also asked them to note any distinctions between supplies covered in home health and outpatient

[7]For purposes of this study, we defined home health care as a situation in which medical supplies are provided to the patient by a home health agency, in accordance with a plan provided by a physician. We defined outpatient care as any situation, in which a patient receives medical supplies, that does not require an overnight hospital stay, such as a visit to a doctor's office, or a situation where the patient self-administers the supplies at home, without the assistance of a home health agency.

[8]The Research Review Act of 2004 specifically directed us to determine coverage of ostomy supplies; consequently, we did not include any other items and services that may relate to ostomy care in this study.

[9]In response to the Research Review Act of 2004, we also conducted a study of the problems IBD patients encounter when applying for disability insurance benefits under Title II of the Social Security Act. See GAO: *Social Security Disability Insurance: SSA Actions Could Enhance Assistance to Claimants with Inflammatory Bowel Disease and Other Impairments*, GAO-05-495 (Washington, D.C.: May 31, 2005).

[10]Throughout the remainder of this report, we will refer to District of Columbia as a state and count it as such when describing our survey results.

delivery settings, and to indicate whether they had different coverage policies for adults and children.[11] Our survey was generally based on relevant Medicare coverage standards and provided states with the opportunity to describe how their coverage policies varied from Medicare's policies and to report other pertinent standards they may have established. In addition, our survey included a list of drugs to treat IBD that was developed in consultation with the FDA. Specifically, the survey listed nine brand name drugs and two generic drugs that the FDA told us it had approved to treat Crohn's disease and ulcerative colitis.[12]

We received responses from all of the states and reviewed these data for obvious inconsistency errors and completeness. For responses that were unclear or incomplete, we contacted survey respondents to obtain clarification before conducting our analyses. When necessary, we compared our electronic data files of survey responses to the actual surveys that we obtained from states. Based on these efforts, we determined that the data were sufficiently reliable for the purposes of this report. To obtain detailed background on the specific supplies that are associated with each of the therapies, we also contacted representatives from eight organizations representing patients with IBD, and medical experts. (See app. I for additional information on our scope and methodology.) We conducted our work from December 2004 through November 2005, in accordance with generally accepted government auditing standards.

Results in Brief

Medicare generally provides coverage for three of the five therapies we reviewed—parenteral nutrition, enteral nutrition formula, and ostomy care—for beneficiaries with IBD. Coverage is available in both home health and outpatient delivery settings. Medicare has established standards that must be met for parenteral and enteral nutrition to be covered. Patients must have specific medical conditions in order to receive coverage. For example, Medicare will cover parenteral nutrition for a patient with a severe gastrointestinal condition that impairs

[11]Because Medicare does not cover children, except in very limited circumstances not applicable to this report, such a distinction was not necessary for the Medicare analysis.

[12]The nine brand name drugs listed in our survey were Asacol, Azulfidine, Canasa, Colazal, Dipentum, Entocort, Pentasa, Remicade, and Rowasa. The survey also listed the generic equivalents of two of these drugs, Azulfidine and Rowasa. After we administered our survey, the FDA informed us that it also considers several additional drugs as valid treatments for IBD. These drugs are not discussed in this report.

absorption of nutrients, and enteral nutrition for a patient with a functioning gastrointestinal tract who cannot maintain adequate weight and strength because food cannot reach the digestive tract. In addition, Medicare requires such medical conditions to be well documented in order to cover these two therapies. Medicare has one coverage standard governing the provision of ostomy care—the beneficiaries receiving these supplies have had an ostomy. Medicare does not cover medically necessary food products. Similarly, Medicare does not cover most drugs used by IBD patients—these drugs are typically self-administered prescription drugs, and currently, they are not covered by the program. However, medically necessary drugs, including those that are self-administered, will be covered by Medicare's voluntary prescription drug benefit, which becomes effective in January 2006. Unlike Medicare, each state Medicaid program covers, to some extent, at least one of the five therapies, including medically necessary food products and drugs used to treat IBD. Our survey results also indicated that each state Medicaid program has its own coverage standards; however, most states' standards are generally comparable to Medicare's coverage for parenteral and enteral nutrition and ostomy care.

Once Medicare coverage standards are met, the program will generally cover—with very few restrictions—all medically necessary formulas, administration supplies, and equipment associated with both parenteral and enteral nutrition. Medicare will also provide beneficiaries who have had ostomies with supplies for their ostomy care. Although Medicare has established "usual maximum quantities" of supplies that typically meet the needs of ostomy patients, these amounts may be exceeded if the need is justified. Our survey of Medicaid programs shows variation in the specific supplies covered for the five therapies. We found that states generally cover supplies associated with parenteral nutrition therapy. Similarly, states cover most enteral nutrition supplies. However, states' coverage of specific ostomy supplies varies. We found that twenty-four states covered all of the ostomy supplies listed in our survey in both home health and outpatient delivery settings. Fifteen of these 24 states imposed limits and monetary caps on these supplies. Further, 10 of these 15 states reported that, for certain supplies, the supply limits and monetary caps are rarely or never exceeded. Most states—46—reported covering at least some medically necessary food products with oral nutritional formulas being the item most commonly covered. Finally, our survey results show that Medicaid programs generally cover the brand name drugs and generic equivalent drugs listed in our survey to treat IBD.

In commenting on a draft of this report, CMS said that we correctly described the Medicare coverage policies for parenteral and enteral nutrition and ostomy supplies and provided clarification for our description of Medicare's coverage policy for prescription drugs that are not self-administered. It also said that as it proceeds with policy development, it will continue to give consideration to access issues that affect Medicare beneficiaries and Medicaid recipients in their treatment of IBD.

Background

IBD refers to Crohn's disease and ulcerative colitis.[13] Crohn's disease can involve any area of the gastrointestinal tract but most commonly affects the small intestine, which is responsible for the body's absorption of most needed nutrients, and the beginning of the large intestine, or colon. This inflammation can result in excessive diarrhea, severe rectal bleeding, anemia, fever, and abdominal pain. In addition, malnutrition or nutritional deficiencies are also common among Crohn's disease patients, particularly if the disease is extensive and of long duration. Two-thirds to three-quarters of patients with Crohn's disease will require surgery—in most cases, to remove the diseased segment of the bowel and any associated abscess. In some cases, an ostomy to remove the colon also may be required. However, surgery is not considered a cure for Crohn's disease patients because the disease frequently recurs. Ulcerative colitis only affects the colon. This condition causes diarrhea and bleeding, and can ultimately lead to colon cancer. In one-quarter to one-third of patients with ulcerative colitis, medical therapy is not completely successful or complications arise. Under these circumstances, an ostomy operation may be performed. Because inflammation in ulcerative colitis is confined to the colon, the disease is curable by this operation.

IBD may occur at any age, but it most commonly develops between the ages of 10 and 30. One-third of IBD patients develop symptoms before adolescence. In such cases, the disease poses special problems because it can impair children's bodies' ability to absorb nutrients and thus adversely affects their growth and development.

[13]About 10 percent of IBD patients exhibit symptoms of both Crohn's disease and ulcerative colitis. This condition is referred to as indeterminate colitis.

IBD patients, depending on each individual's unique circumstances, may rely on one or more of the following key therapies in either home health or outpatient delivery settings to manage their disease:

- Parenteral nutrition is the intravenous administration of nutrients through a catheter that carries liquid nutrients directly into the bloodstream, where they are absorbed by the body, entirely bypassing the gastrointestinal tract. It is typically used to treat patients with severe cases of IBD. In such instances, patients' gastrointestinal tracts cannot tolerate nutrition by mouth or a feeding tube. The provision of parenteral nutrition allows the intestines to rest and heal, and may relieve acute attacks and delay or avoid the need for surgery. Supplies used in parenteral nutrition include parenteral nutrition solutions and various products necessary to administer the solutions to the patient, such as infusion pumps and intravenous poles. Parenteral nutrition supply kits include supplies necessary to transfer the solution to the infusion pump, such as tubes, and sterilization pads. Parenteral nutrition administration kits include supplies necessary to transfer the solution from the pump to the patient, such as intravenous catheters, dressings, tapes, antiseptics, and sterile gloves.[14]

- Enteral nutrition is indicated for patients with a functioning gastrointestinal tract but whose oral nutrient intake is insufficient to meet their nutritional needs. Enteral nutrition employs a feeding tube to deliver a liquid nutritional formula to the stomach or small intestine—it is administered either through the nose or directly through the abdominal wall into the gastrointestinal tract. For IBD patients, and particularly for Crohn's disease patients whose inflamed small intestine may not allow them to absorb enough nutrients, this method—either used alone, or in combination with food or liquids taken orally—may restore good nutrition to patients weakened by severe diarrhea and poor nutrition. In addition, according to gastrointestinal disease experts, enteral nutrition may have therapeutic effects as well, by inducing remission. Supplies used in enteral nutrition include enteral formulas and supplies necessary to administer this therapy, such as enteral nutrition infusion pumps, intravenous poles, catheters, and tubes. Enteral feeding supply kits include supplies necessary to administer the formula to the patient, such as syringes, tubing to transfer the formula to the catheter, tube connectors, and sterile gloves.[15] Tubing that goes inside the patient's body to administer the

[14]Specific supplies included in the parenteral supply kits and administration kits can vary, depending on the supplier.

[15]Specific supplies included in the enteral feeding supply kits can vary depending on specific patient needs.

nutrients—i.e., nasogastric tubing that delivers the formula to the patient's gastrointestinal system through the nose, or gastrostomy tubing that delivers the formula through a surgically created opening in the stomach—is also necessary. Other supplies needed may include additives, such as fiber, to thicken enteral formulas.

- Medically necessary food products are products that can be taken orally. They include food supplements, such as the formulas used in enteral nutrition, and prescription strength vitamins. For example, because Crohn's disease and surgical procedures that remove parts of the small intestine can inhibit absorption of vitamins, fats, and other important nutrients, taking certain supplements, such as fish oil, antioxidants, and mineral supplements, may be beneficial for patients with Crohn's disease.

- Medications are often required to treat Crohn's disease and ulcerative colitis. The FDA has approved both brand name drugs and generic drugs to treat IBD. These drugs are typically self-administered and taken to reduce inflammation in the intestinal wall. In addition, there are other medications approved by the FDA—but not specifically to treat IBD—that may be effective in treating the disease.[16]

- IBD patients who have had an ostomy operation need to use specific supplies for their ostomy care. An ostomy surgery creates an opening in the abdomen. This opening, called a stoma, permits digested food to exit the body. In most cases, this type of surgery results in a permanent opening.[17] Subsequent to the operation, ostomy patients need certain supplies to manage the abdominal opening and the waste. For example, the patient wears a pouch over the opening to collect the waste and then empties the pouch as needed. Other necessary supplies include skin barriers to protect the skin and irrigation and fluid discharge supplies.

Medicare pays for beneficiaries' medically necessary health care needs as long as they fit into one of the broadly-defined categories of benefits established in the Social Security Act. Among other things, these categories include commonly used medical services and supplies such as physician visits, inpatient hospital stays, diagnostic tests, durable medical

[16]The prescribing of a drug for treatments other than those specified on the label approved by FDA is referred to as off-label use.

[17]Not all ostomies are permanent. According to one gastrointestinal expert, about 20 percent of ostomies are temporary. A temporary ostomy is more common among younger patients, while Medicare patients are more likely to have permanent ostomies.

equipment, and prosthetic devices. While the act provides for broad coverage of many medical and health care services, it does not provide an exhaustive list of all services covered.[18] Similarly, the act generally does not specify which medical devices, surgical procedures, or diagnostic services the program covers. In addition, the act states that the program cannot pay for any supplies or services that are not "reasonable and necessary" for the diagnosis and treatment of an illness or injury.[19] With the Social Security Act serving as the primary authority for all coverage provisions, CMS has established coverage policies that specify the procedures, devices, and services that are covered in the broad benefit categories established in the act.[20] In addition, CMS has established the criteria used to determine whether these supplies are reasonable and necessary for a beneficiary's treatment. CMS's national coverage determinations (NCDs) describe the circumstances for Medicare coverage for a specific medical service, procedure, or device and they outline the conditions for coverage.[21] CMS interpretive manuals further define when and under what circumstances items or services may be covered.

Claims administration contractors are required to follow CMS's national coverage policies. However, if an NCD does not specifically exclude or limit coverage for an item or service, or if the item or service is not mentioned at all in an NCD or CMS manual, it is up to the contractors to determine whether they will cover a particular item or service within their geographic area. This is often done through a local coverage determination

[18]Congress gave the Secretary of Health and Human Services the authority to decide which specific supplies and services within these categories are covered by Medicare.

[19]Specifically, the law states that Medicare cannot pay for any supplies or services that are not "reasonable and necessary for the diagnosis and treatment of an illness or injury or to improve functioning of a malformed body part." 42 U.S.C. §1395y(a)(1)(A).

[20]The Secretary of Health and Human Services delegated the legal authority to specify which procedures, devices, and services are covered in the Social Security Act's benefit categories to CMS and its contractors.

[21]NCDs are typically issued as program instruction and are binding on all Medicare claims administration contractors. NCDs must be made available for public comment prior to finalization. The law also requires proposed NCDs to be reviewed by either the Medicare Coverage Advisory Committee or outside clinical experts. NCDs are also binding on Administrative Law Judges during the claims appeal process.

(LCD).[22] LCDs specify under what circumstances the item or service is considered to be reasonable and necessary, in accordance with the Social Security Act, and are supplemented by additional instructions from the contractors. LCDs related to durable medical equipment, prosthetic devices, orthotics, and a number of other supplies are made by the DMERCs—the four CMS claims administration contractors that process claims exclusively for these supplies. The DMERCs are required by CMS to coordinate their coverage development process with one another and they publish identical LCDs.[23]

Medicaid coverage policies vary by state. While all state Medicaid programs must pay for certain services, such as inpatient and outpatient hospital services, and early and periodic screening, diagnostic, and treatment services for individuals under the age of 21, states have broad discretion in setting up their Medicaid programs. They may set different eligibility standards, scope of services, and payments, and can elect to cover a range of optional populations and benefits.[24]

[22]LCDs are considered administrative and educational tools that provide guidance to the public and medical community within the contractor's jurisdiction, and assist providers in submitting correct claims for payment. When developing LCDs, contractors consider medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community. LCDs must also be consistent with all statutes, rulings, regulations, and national coverage, payment, and coding policies. During the claims appeal process, administrative law judges may consider LCDs, but they are not bound by them.

[23]The Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) defined the term LCD as including only decisions as to whether items or services are "reasonable and necessary." Pub. L. No. 106-554, app. F, § 522(a), 114 Stat. 2763A, 2763A-546. Prior to the passage of BIPA, the DMERCs had issued documents called Local Medical Review Policies (LMRPs) to indicate all coverage information for parenteral and enteral nutrition and ostomy supplies, including a determination of whether items and services are reasonable and necessary. CMS has required the DMERCs to convert existing LMRPs to LCDs. According to CMS guidance, these new LCDs should contain only determinations on reasonableness and necessity, and other instructions from the DMERCs, such as coding guidelines, are issued in other publications called policy articles. As of September 2005, the DMERCs had issued LCDs and related policy articles for enteral nutrition and ostomy supplies, but not for parenteral nutrition. Throughout the report, we use the term local coverage policy to describe all DMERC decisions and instructions, regardless of whether they are found in an LMRP, LCD, or policy article.

[24]Optional supplies and services include, among others, prescribed drugs, prosthetic devices, home health care services, dental services, and physical therapy.

Coverage of IBD Therapies Is Subject to Medicare and Medicaid Standards

Medicare generally covers parenteral and enteral nutrition and ostomy care in home health and outpatient delivery settings for beneficiaries who meet certain medical standards. These three IBD therapies are included in specific benefit categories established by the Social Security Act—primarily the prosthetic devices benefit category, and in the case of ostomy care provided in a home health care delivery setting, the home health benefit category. Medicare does not cover medically necessary food products or most drugs approved by the FDA that are used to treat IBD. However, in January 2006, Medicare will begin to cover medically necessary drugs when the program's new prescription drug benefit becomes effective. None of the five therapies we examined for this report are mandatory services under Medicaid. However, our survey of Medicaid programs indicates that most of these programs provided eligible individuals some coverage for all five therapies. We also found that coverage standards that Medicaid recipients must meet to receive these therapies varied by state. Table 1 summarizes the number of states covering each of the five therapies. (See app. II for specific information on each state Medicaid program's coverage of these therapies.)

Table 1: State Medicaid Programs That Reported Coverage of Five IBD Therapies for Adults and Children

	Parenteral nutrition	Enteral nutrition	Ostomy care	Medically necessary food products	Drugs[a]
Adults and children	50	49	51	40	50
Adults only	0	0	0	0	1
Children only	1	1	0	6	0
Not covered for adults or children	0	1	0	5	0
Total	**51**	**51**	**51**	**51**	**51**

Source: GAO survey of state Medicaid programs.

[a]For this analysis, we are defining states' coverage of drugs to treat IBD as states' coverage of at least one of the brand name drugs or generic equivalent drugs listed in our survey.

Medicare and Medicaid Coverage Standards for Parenteral Nutrition

Our analysis showed that Medicare and state Medicaid programs will generally cover parenteral nutrition as follows:

Medicare: Medicare generally covers parenteral nutrition, as CMS has determined that it falls under the prosthetic devices benefit category, established in the Social Security Act.[25] CMS's coverage standards for parenteral nutrition therapy are outlined in both an NCD and in local coverage policy.[26] Coverage is provided in both home health and outpatient delivery settings. The NCD requires the patient to have a severe pathology of the alimentary tract[27] that does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition. A period of hospitalization is required to initiate coverage for parenteral nutrition and to train the patient in how to prepare, manage, and administer the formula and equipment. The NCD also requires a physician's written order or prescription and sufficient medical documentation to show that the prosthetic device coverage requirements are met and that parenteral nutrition therapy is medically necessary. In addition, before approving coverage, the carrier must agree that a particular condition qualifies for parenteral nutrition therapy. Medicare will approve coverage of parenteral nutrition at periodic intervals of no more than three months. In addition, Medicare will pay for no more than one month's supply of nutrients at a time.

Building upon the coverage standards in the NCD, the DMERCs' local coverage policy on parenteral nutrition provides significantly more detailed requirements. The policy consists of specific clinical criteria for showing that parenteral nutrition is considered reasonable and necessary. Like the NCD, the local policy specifies that a patient must either have a condition involving the small intestine that significantly impairs the absorption of nutrients, or a disease of the stomach or intestine that impairs the ability of nutrients to be transported through the gastrointestinal system. The local coverage policy also requires that the

[25]Covered prosthetic devices are "devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices." 42 U.S.C. § 1395x(s)(8).

[26]Per CMS requirements, DMERCs have to establish identical coverage policies; therefore, their policies are worded the same. For simplification purposes, we will refer to these policies as a single policy throughout the rest of the report.

[27]The alimentary tract consists of the passage that extends from the mouth to the anus and is responsible for the movement of food through the body and its digestion and absorption.

patient's inability to maintain proper weight and strength necessitates intravenous nutrition, and that the patient is unable to be treated through either diet modification or with drugs.[28] It also describes specific clinical conditions that meet these criteria. For patients who do not meet the standards for these clinical conditions, coverage for parenteral nutrition will be considered on an individual basis if detailed documentation is submitted. However, some patients with moderate abnormalities may not be covered unless they have experienced an unsuccessful trial of enteral nutrition.

Medicaid: Our survey responses indicated that all states provide some parenteral nutrition coverage for children and all but one—Georgia—provide such coverage for adults. However, Georgia reported that it would consider coverage for adults under an appeal process to its medical director. Our results showed variation among states in the standards used to determine coverage for parenteral nutrition. Seven states used all six of the coverage standards listed in our survey to determine whether Medicaid would cover parenteral nutrition therapy for adults and children.[29] The remaining 44 states used a variety of the six coverage standards. For example, Arkansas, California, Kentucky, North Carolina, and Oregon require individuals to meet three of the six standards, including pathology and documentation. Forty-five states indicated that before covering parenteral nutrition therapy for individuals, they would require some form of documentation, such as proof of a medical condition. Forty-one of these same states also required individuals to have a severe pathology of the gastrointestinal tract that would not allow absorption of sufficient nutrients to maintain weight and strength. Only one state—Minnesota—

[28]The local coverage policy considers a total caloric daily intake (through parenteral, enteral and oral nutrition) of 20-35 calories per kilogram per day sufficient to achieve or maintain appropriate body weight.

[29]For purposes of this survey, we used Medicare's coverage standards for parenteral nutrition therapy as a basis for developing questions about the state Medicaid programs' coverage standards. The primary Medicare coverage standards for parenteral nutrition therapy that we identified are as follows: (1) Patient has to have a severe pathology of the gastrointestinal tract that does not allow absorption of sufficient nutrients to maintain weight and strength; (2) Patient has to have a permanent impairment of the gastrointestinal tract, i.e., lasting at least 3 months; (3) The patient's maintenance of weight and strength needs to be through intravenous nutrition only; (4) Other therapies—such as enteral nutrition and medication—need to have failed in order for the state to cover parenteral nutrition; (5) Patient must have a specific clinical condition to qualify for coverage of parenteral nutrition; and (6) Specific documentation—such as proof of medical condition, duration of gastrointestinal impairment, or list of medications used—has to be indicated in the patient's medical record.

provided coverage for parenteral nutrition therapy without listing any specific conditions that individuals must meet to receive therapy. For details on specific coverage standards for parenteral nutrition therapy by state, see app. III.

Medicare and Medicaid Coverage Standards for Enteral Nutrition

Our analysis showed that Medicare and most state Medicaid programs will generally cover enteral nutrition as follows:

Medicare: Medicare covers enteral nutrition under the prosthetic devices benefit category. The NCD coverage standards for enteral nutrition are very similar to those for parenteral nutrition, with the primary difference being the requirements involving the patient's clinical condition. As with parenteral nutrition, coverage for enteral nutrition is provided in both home health and outpatient delivery settings. However, for enteral nutrition, the patient may have a functioning gastrointestinal tract but must be unable to maintain appropriate weight and strength due to pathology to, or the nonfunction of, the structures that normally permit food to reach the digestive tract. The only other differing requirement in the NCD between the two therapies is that there is no hospitalization requirement for a patient seeking Medicare coverage for enteral nutrition. The NCD also requires a physician's written order or prescription and sufficient medical documentation to show that the prosthetic device coverage requirements are met and that enteral nutrition therapy is medically necessary.

The local coverage policy on enteral nutrition is simpler than the local policy for parenteral nutrition. It provides coverage for enteral nutrition so long as adequate nutrition is not possible by either dietary adjustment or oral supplements. Tube feedings of enteral nutrition must be required to provide sufficient nutrients to maintain weight and strength commensurate with the patient's overall health status due to either one of two conditions: (1) a permanent non-function or disease of the structures that normally permit food to reach the small bowel, or (2) a disease of the small bowel which impairs digestion and absorption of an oral diet. However, coverage is possible for patients with partial impairments, such as a Crohn's disease patient who requires prolonged infusion of enteral nutrients to overcome a problem with absorption. Enteral nutrition products administered orally are not covered.

Medicaid: Forty-nine states reported that they provided some coverage for enteral nutrition therapy for both adults and children. One state—Oklahoma—indicated that it provided coverage for children, but not for

adults. West Virginia responded that it did not cover this therapy at all. Analysis of survey results also indicated that there was some variation in coverage standards used among the 49 states that covered enteral nutrition therapy for adults and children. Six states reported that they cover enteral nutrition therapy for patients who meet all six coverage standards listed in our survey.[30] The remaining states used a variety of the six coverage standards. For example, Arizona, Colorado, Michigan, New Mexico, and Wisconsin indicated that they use five of the six standards—these states did not require the patient to have a permanent condition in order to be covered for this therapy. Washington reported that, in addition to subjecting individuals to most of the criteria listed in our survey, it also requires prior approval of enteral nutrition therapy based on documentation showing that the therapy is medically necessary and outlining why traditional food is not appropriate. We also found that for both adults and children, 45 of the 49 states that cover enteral nutrition therapy require individuals to have specific documentation in their medical records before the states would render coverage. We also found that 12 states had less restrictive coverage standards for children. See app. IV for more details on enteral nutrition therapy and supplies coverage standards for each state.

Medicare and Medicaid Coverage Standards for Ostomy Care

Medicare and Medicaid provide at least some coverage of ostomy care. In outpatient delivery settings, Medicare covers ostomy care for IBD patients under its benefit category of prosthetic devices—similar to parenteral and enteral nutrition. In home health care delivery settings, Medicare covers

[30]For purposes of this survey, we used Medicare's five coverage standards for enteral nutrition therapy as a basis for developing questions about the state Medicaid programs' coverage standards. The primary Medicare coverage standards for enteral nutrition therapy that we identified are as follows: (1) Patient has to have a pathology or non-function of the structures that normally permit food to reach the small bowel (e.g., inability to swallow), which impairs the ability to maintain weight and strength; (2) The impairment has to be considered a permanent condition, (i.e., lasting at least 3 months); (3) Patient's condition must necessitate tube feedings to provide sufficient nutrients to maintain weight and strength (i.e., patient must be unable to obtain adequate nutrition through dietary adjustment and/or oral supplements); (4) Enteral nutrition for patients with partial impairments (e.g., Crohn's disease patient who requires prolonged infusion of enteral nutrients to overcome an absorption problem) is possible; and (5) Specific documentation has to be provided in the patient's medical record. In addition, although Medicare does not cover enteral nutrition products that are administered orally, we asked states whether they have established a sixth standard by covering such products and related supplies.

this therapy as a home health benefit.[31] While there is no NCD for ostomy care, the four DMERCs have established a local coverage policy for these supplies. According to the policy, the only Medicare coverage standard is that the patient must have had an ostomy. Similarly, all state Medicaid offices, according to our survey responses, provide coverage of ostomy care for adults and children who have had ostomies.

Medicare and Medicaid Coverage Standards for Medically Necessary Food Products

Medicare does not cover medically necessary food products because such supplies are not included in any of the benefit categories contained in the Social Security Act.[32] On the other hand, according to our survey results, Medicaid provides at least some coverage of medically necessary food products to its recipients in 46 of the states. Nevada, North Carolina, Ohio, Utah, and West Virginia were the five states that did not provide any coverage for medically necessary food products. Of those states reporting that they provided coverage, 14 also noted that they had a requirement that the individuals receive a certain percentage of their nutrition from oral supplements in order for these supplements to be covered. In some instances, this percentage was as high as 75 to 100 percent. For example, Florida, Georgia, Mississippi, Rhode Island, and South Dakota required some individuals to meet 100 percent of their nutritional requirements from oral supplements; however these individuals did not have to meet all of the other conditions listed in our survey. On the other hand, while North Dakota reported that individuals must receive at least 51 percent of their nutrition from oral supplements, it had the most stringent standards overall because it required that individuals meet all three conditions for coverage listed in our survey.[33] For more information on states' coverage standards for medically necessary food products, see app. V.

[31]Under the home health benefit, Medicare pays for services provided to homebound beneficiaries by a home health agency under the care of a physician. Covered items and services under this benefit include physical therapy, medical supplies, and durable medical equipment as long as they are medically necessary.

[32]In addition, the NCD for parenteral and enteral nutrition specifically excludes "nutritional supplementation" from coverage.

[33]For purposes of this survey, states were asked to respond to three coverage standards as summarized from discussions with health experts and our review of relevant literature as follows: (1) medically necessary food products are covered if they are an essential source of nutrition; (2) medically necessary food products are covered only for specific conditions; and (3) medically necessary food products are covered only during the period following hospitalization.

Medicare and Medicaid Coverage Standards for Drugs to Treat IBD

Medicare does not generally cover medications that are self-administered, including drugs approved by the FDA to treat IBD. Coverage is not provided because such self-administered medications are not included in any of the benefit categories contained in the Social Security Act.[34] However, in 2003, the Social Security Act was amended, establishing a new voluntary prescription drug benefit for Medicare beneficiaries that will become effective in January 2006.[35] At that time, Medicare will begin to cover self-administered drugs approved by the FDA to treat IBD.[36]

States generally provide some coverage of drugs approved by the FDA to treat IBD. Generally, before covering a drug, states require that: (1) a physician or licensed practitioner writes the prescription; (2) a licensed pharmacist or licensed authorized practitioner dispenses the prescription; and (3) the drug is dispensed on a written prescription that is recorded and maintained in the pharmacist's or practitioner's records. Our survey did not ask state Medicaid programs about the standards used to determine coverage of drugs to treat IBD because state Medicaid programs are not required to cover prescription drugs.

Our survey also asked state officials whether their Medicaid programs cover the off-label use of drugs to treat IBD. Responses to this question varied. Nineteen states responded that they had no policy for the use of

[34]Specifically, outpatient drugs and biologicals are covered when they are furnished incident to a physician's professional service, provided that they are not usually self-administered by the patient. See 42 U.S.C. § 1395x(s)(2)(A). Therefore, medications used to treat IBD therapy that are self-administered are not covered by Medicare, but those administered by a physician in a clinical setting may be covered as long as they are "not usually self-administered." CMS has published a general policy for determining whether a drug meets these statutory requirements, but the ultimate decision on a particular drug is made by each Medicare claims administration contractor. Of the drugs and biologicals used to treat IBD, only one would likely be considered "not usually self-administered" under CMS guidelines—Remicade—because it is given intravenously. We did not survey the Medicare claims administration contractors to determine whether each has issued coverage policies on Remicade.

[35]Medicare Prescription Drug, Improvement, and Modernization, Act, Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2071-2152 (codified at 42 U.S.C. §§ 1395w-101 to 1395w-152).

[36]Under the new prescription drug benefit, private plans will contract with Medicare to provide drug coverage for Medicare beneficiaries. In general, outpatient prescription drugs will be covered if the drug is either (1) on the specific plan's formulary, or (2) determined to be medically necessary. The medically necessary determination is made through Medicare's exception/appeals process, which requires the plan to cover any drug that is considered medically necessary for the beneficiary even if it is not on the plan's formulary. CMS has also indicated that the drug plans may cover off-label uses of drugs, if they are prescribed for medically accepted indications; but they are not required to do so.

off-label drugs or that their state did not cover off-label use. Many of these respondents wrote that they only covered drugs approved by the FDA to treat IBD. Twenty-four states indicated that they cover off-label drug use. However, 20 of these 24 states responded that they would only cover the drug under certain conditions. Many of these states reported that individuals obtaining such prescriptions must receive prior approval or documentation justifying medical necessity. Michigan has the most detailed off-label coverage policy of all the states; it indicated that off-label drugs must receive prior authorization as well as documentation outlining the (1) diagnosis, (2) medical reason why the individual cannot use another covered drug; (3) results of therapeutic alternative medication tried, and (4) medical literature citations supporting the off-label usage. The remaining eight states did not respond to this question.

Variation in Medicare and Medicaid Programs' Coverage of Specific Supplies Related to IBD Therapies

Once coverage standards are met, Medicare generally covers all medically necessary supplies for the administration of parenteral and enteral nutrition and ostomy care—the three therapies that this program covers. On the other hand, our survey of Medicaid programs showed that although most states provide eligible individuals at least some coverage of each of the five therapies addressed in this report, the specific supplies that states will pay for vary and may be subject to restrictions. According to our survey results, most states will cover necessary supplies related to parenteral and enteral nutrition with only slight variations for the specific supplies supplied. We also found that, while all states provided some coverage of ostomy care, the specific supplies that states cover varied. Our survey also showed that, while most states will cover at least one of the five medically necessary food products listed in our survey, no state covers all of them for both adults and children. Finally, we found that most Medicaid programs generally covered many of the brand name drugs and equivalent generic drugs listed in our survey.

Parenteral Nutrition Supplies Covered by Medicare and Medicaid

Medicare will generally cover parenteral nutrition therapy supplies, such as nutrients and administration supplies, for beneficiaries who have met applicable coverage standards. Specifically, according to the applicable local coverage policy, Medicare will cover necessary parenteral nutrition solutions. In addition, when coverage requirements for parenteral nutrition are met, Medicare will also pay for one supply kit and one administration kit for each day that parenteral nutrition is administered, if such kits are medically necessary and used. Medicare will also cover infusion pumps—only one pump will be covered at any one time.

The local coverage policy also outlines several documentation requirements for ensuring that the patient's medical records—including test reports and records from the physician's office, home health agency, hospital, nursing home, and other health care professionals—establish the medical necessity for the care provided. These records must be made available to the DMERC upon request. In addition, an order for each item billed and a certificate of medical necessity[37] must be signed and dated by the treating physician, kept on file by the supplier, and be made available to the DMERC. Besides the initial certification, there are also documentation requirements if recertifications or revised certifications are necessary.[38]

States' Medicaid coverage of the five most commonly used parenteral nutrition therapy supplies shows some variation, depending on the item and the delivery setting. As table 2 shows, parenteral nutrition therapy supplies—such as the infusion pump—are covered by more states than the parenteral nutrition solution. In addition, more states reported that they cover parenteral nutrition therapy supplies in outpatient delivery settings than in home health delivery settings. There was little difference in the coverage of various supplies between adults and children.

[37]A certificate of medical necessity is required for Medicare reimbursement for 14 types of durable medical equipment and supplies. This form, which should be personally signed by the treating physician or midlevel practitioner—i.e., a nurse practitioner or physician assistant trained to provide medical assistance that otherwise might be performed by a physician—to attest to the accuracy of the information contained on the form, documents medical necessity.

[38]Based on the clinical condition involved, there may also be other documentation requirements for parenteral nutrition therapy, such as evidence of malnutrition, a failed tube feeding trial, attempts to feed orally or enterally, and caloric intake and output. It may also be necessary to provide reports of small bowel motility studies, a list of medications used to treat certain conditions, and laboratory data such as a fecal fat test documenting malabsorption.

Table 2: State Medicaid Programs That Reported Payment of Common Parenteral Nutrition Therapy Supplies for Adults and Children in Home Health and Outpatient Delivery Settings

	Adults		Children	
Supplies	**Home health**	**Outpatient**	**Home health**	**Outpatient**
Parenteral nutrition solution	34	42	35	44
Parenteral nutrition supply kit	35	43	36	44
Parenteral nutrition administration kit	36	45	37	46
Parenteral nutrition infusion pump	40	46	40	47
Intravenous pole	39	43	40	45

Source: GAO survey of state Medicaid programs.

Further analysis of survey results revealed that 28 states covered all supplies in both home health and outpatient delivery settings for adults and children. For more specific information on the parenteral nutrition supplies covered by each state, see app. VI.

Enteral Nutrition Supplies Covered by Medicare and Medicaid

Medicare will generally cover supplies associated with enteral nutrition therapy for beneficiaries who meet coverage standards. According to the enteral nutrition local coverage policy, Medicare will cover all enteral formulas for covered beneficiaries.[39] In addition, Medicare will also cover medically necessary equipment and supplies for this therapy, such as feeding supply kits and pumps that are associated with the specific method of administration used by the patient. However, a few limitations apply. For example, claims for more than one type of kit delivered on the same date will be denied as not medically necessary. Similarly, Medicare will rarely consider the use of more than three nasogastric tubes or one gastrostomy tube over a 3-month period as medically necessary.

The local coverage policy also outlines several documentation requirements for coverage of enteral nutrition supplies. Similar to the parenteral nutrition local policy, the enteral nutrition policy requires that

[39]For special formulas, the medical necessity will need to be justified for each patient. Otherwise, Medicare payment will be based on the allowance for the least costly medically appropriate alternative.

the patient's medical record reflect the need for the care provided. It also has requirements associated with the certification of enteral nutrition. For example, if the physician orders enteral nutrition supplies for a longer period of time than is indicated on the original certificate of medical necessity, the enteral nutrition policy will require recertification. However, the enteral nutrition policy generally has fewer documentation requirements than that of parenteral nutrition.

Based on our survey, state Medicaid programs' payment for seven of the most commonly used enteral nutrition therapy supplies varies depending on the type of product, delivery setting, and whether the patient is an adult or a child. Table 3 shows that states reported that their Medicaid programs pay for enteral feeding supply kits and tubing more than other therapy supplies. In addition, more states pay for enteral supplies for children than adults and more states pay for supplies in outpatient delivery settings than in home health delivery settings.

Table 3: State Medicaid Programs That Reported Payment for Common Enteral Nutrition Therapy Supplies for Adults and Children in Home Health and Outpatient Delivery Settings

	Adults		Children	
Supplies	**Home health**	**Outpatient**	**Home health**	**Outpatient**
Enteral formula	35	42	37	44
Enteral feeding supply kit	40	45	43	46
Tubing	41	43	42	46
Additive for enteral formula	22	28	24	30
Enteral nutrition infusion pump	38	40	40	42
Intravenous pole	38	40	40	42
Percutaneous catheter/tube	30	33	31	38

Source: GAO survey of state Medicaid programs.

Further analysis revealed that 15 states pay for all seven supplies listed in our survey in both home health and outpatient delivery settings for adults and children. Thirty states pay for five or more enteral nutrition supplies for adults and children in these same settings. We also found that additives for enteral formula, such as fiber, are the least covered product, with only 21 states covering it in both home health and outpatient delivery settings

for adults and children. For specific results of enteral nutrition supplies provided by each state, see app. VII.

Ostomy Supplies Covered by Medicare and Medicaid

Medicare covers all of the types of ostomy supplies used by IBD patients who require ostomy care. However, there are two restrictions regarding the types of ostomy supplies covered. First, Medicare will only provide a beneficiary with one type of liquid skin barrier[40] if one is needed—either a liquid or spray barrier, or individual wipes. Second, Medicare will only pay for one type of drainage supply—a stoma cap, a stoma plug, or gauze pads—on a given day. These restrictions are imposed by the DMERCs in a local coverage policy, which also specifies the "usual maximum quantity" of supplies that typically meet the needs of ostomy patients for a specific time period (generally for either 1 or 6 months) for each of the most commonly used ostomy supplies.[41] However, according to the four DMERC medical directors, these quantities only serve as guidelines. Because the need for ostomy supplies can vary substantially among patients,[42] DMERCs may cover supplies that exceed the usual maximum quantities if the need is justified.

Medicare's coverage of ostomy supplies is different for IBD patients who receive care under a home health plan of care than for those who receive it in an outpatient delivery setting.[43] If an IBD patient is being served by a home health agency and is under a home health plan of care, all of the patient's medical supplies, including ostomy supplies, are considered part of the Medicare home health services benefit. This is generally the case even when the IBD is a pre-existing condition unrelated to the immediate

[40]Skin barriers are used to protect the skin around the stoma and to increase overall wear time.

[41]DMERCs have established usual maximum quantities of supplies for those ostomy supplies that are most commonly used because more claims data exist on these supplies and because there is a greater risk of overutilization.

[42]The quantity and type of supplies needed by a patient is determined to a great extent by the type of ostomy, its location, its construction, and the condition of the skin surface surrounding the stoma. There will be variation according to individual patient need as well individual needs over time.

[43]A United Ostomy Association survey of Medicare beneficiaries conducted in late 2004 showed that 45 percent of the respondents had received some kind of home health care during a recent 3-year period.

reason for home health care, such as hip replacement surgery.[44] Medicare pays a fixed amount determined under a prospective payment system to the home health agency for the cost of all covered home health visits, including ostomy supplies delivered during these visits.[45] The home health agency is obligated to provide the beneficiary with the necessary ostomy supplies, which are bundled with all other necessary home health services. The home health agency selects the type of ostomy products to be used and if the patient wishes to use different products, the patient must do so at his or her own expense. This practice can be contrasted to the outpatient delivery setting, where the products are generally selected by the patient, or the patient's doctor.[46]

All states responded that their Medicaid programs pay for ostomy supplies for adults and children who have had ostomies; however the range of supplies covered varied. Because of the relatively large number of supplies commonly used by ostomy patients we grouped these supplies in nine categories, based on input from a representative of the United Ostomy Association. Table 4 shows the median percent of states covering ostomy supplies in home health and outpatient delivery settings, after they have been placed in these categories. For example, for the 14 supplies in the drainable pouch with standard barrier supplies category—half of supplies are covered by at least 84 percent of states in home health delivery settings and 85 percent of states in outpatient delivery settings. In general,

[44]According to the United Ostomy Association, almost two-thirds of the individuals who have ostomies and are receiving home care services, are receiving these services for reasons unrelated to their ostomy.

[45]The Balanced Budget Act of 1997 mandated the implementation of the prospective payment system for home health agencies. Pub. L. No. 105-33, § 4603(a), 111 Stat. 251, 467-72. Under this system, home health agencies receive a single payment, adjusted to reflect the care needs of the patient, for delivering up to 60 days of care, called a home health episode. This episode payment is based on the historical national average cost of providing care, not on a home health agency's actual costs of treating any given patient. The episode payment is intended to cover the average costs of all home health visits and medical supplies provided during the episode.

[46]We previously reported that, although Medicare's home health payment includes the average costs of nonroutine medical supplies, including ostomy supplies, this payment may not reflect variation in supply costs across types of patients. Home health agencies may be paid the same amount for treating patients with quite different supply costs. Patients who require costly supplies may have problems accessing home health care, may have to switch supplies, or have a limited number of supplies provided to them during their period of home care. In addition, the agencies that treat them may be financially disadvantaged. See GAO: *Medicare Home Health Payment: Nonroutine Medical Supply Data Needed to Assess Payment Adjustments*, GAO-03-878 (Washington, D.C., August 15, 2003.)

states' coverage of ostomy supplies was greater in outpatient, than in home health delivery settings. For more details on the individual ostomy supplies included in each category and the percent of states covering each supply, see app. VIII.

Table 4: Median Percent of State Medicaid Programs That Reported Covering Ostomy Supplies in Home Health and Outpatient Delivery Settings

Ostomy categories (number of supplies)	Median percent of states that cover supplies in each category in home health delivery settings	Median percent of states that cover supplies in each category in outpatient delivery settings
Drainable pouch with extended wear barrier supplies (2 supplies)	84	88
Drainable pouch with standard barrier supplies (14 supplies)	84	85
Irrigation supplies (6 supplies)	82	84
Fluid discharge management item (1 item)	75	75
Adhering pouch barrier supplies (2 supplies)	85	90
Extended wear barrier supplies (5 supplies)	84	86
Barrier-skin protection supplies (13 supplies)	86	88
Closed pouch supplies (11 supplies)	84	88
Other accessories (15 supplies)	80	82

Source: GAO survey of state Medicaid programs.

Note: Individual supplies under each category appear in app. VIII.

Twenty-four states reported covering all of the ostomy supplies listed in our survey in both delivery settings. Nine of the 24 states that covered all supplies imposed no supply limits or dollar caps on individuals. The remaining 15 states reported that they had supply limits or dollar caps; however five of these states—Arizona, Hawaii, North Dakota, Rhode

Island, and Virginia—added that they often allowed individuals to exceed these limits and caps for certain supplies. For example, one state reported that while it has a supply limit of one box of 50 skin barrier wipes and dollar cap of $9.36 per month, it will often allow individuals to exceed limits and caps. See app. IX for more details on individual states' coverage of supplies, including supply limits and dollar caps, in both home health and outpatient delivery settings.

Medically Necessary Food Products Covered by Medicaid

Unlike Medicare, which does not pay for any medically necessary food products, most state Medicaid programs pay for some products. These products include prescription strength vitamins, oral nutritional formulas, food thickeners, baby foods, blended grocery products, and other supplies. According to our survey, 46 states reported covering at least one of the five products listed in our survey for either adults or children.

As table 5 shows, out of the five food products, state Medicaid programs reported paying for oral nutritional formulas most often. Baby food and other blenderized products were the least common products covered with only four states—Missouri, New Jersey, Tennessee, and Texas—reporting that they paid for these products. In addition, more states paid for medically necessary food products for children than for adults.

Table 5: Number of State Medicaid Programs Covering Medically Necessary Food Products for Adults and Children

	Prescription strength vitamins	Oral nutritional formulas	Food thickeners	Baby food and other blenderized products	Other products
Adults and children	29	36	28	2	12
Children only	6	7	5	2	5
Neither adults nor children	16	8	18	47	34
Total	**51**	**51**	**51**	**51**	**51**

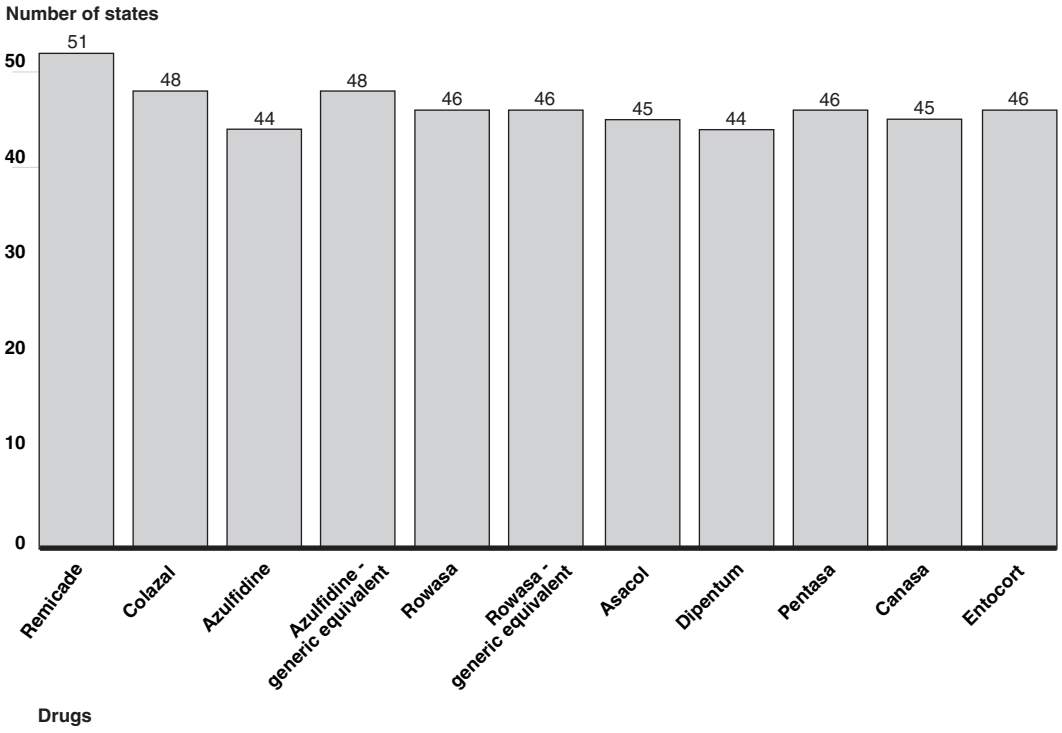
Source: GAO survey of state Medicaid programs.

For more details on states' payment of medically necessary food products, see app. X.

Drugs Covered by Medicaid to Treat IBD

All states reported that their Medicaid programs paid for at least one of the nine brand name drugs or two of the generic drugs that were included in our survey and which were approved by the FDA to treat IBD. Figure 1 shows the number of states covering each drug. The brand name drug Remicade was the most commonly paid for drug, with all states reporting payment.[47] The generic drugs available for Azulfidine and Rowasa were covered by 48 and 46 states respectively.

Figure 1: Number of State Medicaid Programs That Reported Covering Drugs Listed in Our Survey to Treat IBD



Source: GAO survey of state Medicaid programs.

[47]Forty-eight survey respondents reported that their states would cover the brand name drug Remicade. One state—Ohio—wrote that it would cover the drug with prior authorization. The remaining two states—California and Iowa—indicated that they would not cover the drug without prior authorization. Based on these responses, we concluded that all states would cover the drug.

Further analysis revealed that six states—Colorado, Minnesota, Montana, Nevada, Oklahoma, and Wisconsin—reported that individuals must use generic drugs if they are available, before obtaining the equivalent, but more expensive brand name drugs. Three states—California, Iowa, and Ohio—indicated that they would not cover the brand name drug Remicade without prior authorizations. See app. XI for a listing of each state's coverage of drugs listed in our survey to treat IBD for adults and children.

Agency Comments

We provided a draft of this report to CMS. In its written comments, CMS said that it determined that we correctly described the Medicare coverage policies for parenteral and enteral nutrition and ostomy supplies. However, CMS suggested that we clarify our description of Medicare's coverage policy for prescription drugs that are not self-administered. We revised our language to address this concern. It also said that, as it proceeds with policy development, it will continue to give consideration to access issues that affect Medicare beneficiaries and Medicaid recipients in their treatment of IBD. We have reprinted CMS's letter in app. XII.

We also provided FDA with excerpts of the draft concerning drugs it has approved to treat Crohn's disease and ulcerative colitis. FDA responded by e-mail and provided a list that contained several additional drugs it said it considered as valid, labeled, treatments for IBD. FDA's revised list was provided after our survey was administered and these drugs are not discussed in this report. We modified our report to note this.

We are sending copies of this report to the Secretary of Health and Human Services, the Administrator of CMS, the Commissioner of FDA, and other interested parties. In addition, this report will be available at no charge on GAO's Web site at http://www.gao.gov. We will also make copies available to others upon request.

If you or your staffs have any questions about this report, please contact me at (312) 220-7600 or aronovitzl@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report are listed in app. XIII.

Leslie G. Aronovitz
Director, Health Care

Appendix I: Scope and Methodology

In this report, we (1) identify the Medicare and Medicaid coverage standards for five therapies—parenteral nutrition, enteral nutrition formula, ostomy care, medically necessary food products, and drugs approved by the Food and Drug Administration (FDA) for inflammatory bowel disease (IBD); and (2) determine what specific supplies used in these therapies Medicare and state Medicaid programs pay for in home health and outpatient delivery settings. In examining Medicare and Medicaid coverage of these therapies and the related supplies, we considered whether each program would cover these items in both home health and outpatient settings. For purposes of this study, we defined these settings as follows:

- Home health care refers to the situation in which a medical supply is being provided to the individual by a home health aide or others through an arrangement made by a home health agency, in accordance with a plan for furnishing the supply that a physician has established and periodically reviews. The supply is provided through visits made to an individual's residence.

- Outpatient care refers to any situation in which a patient receives a medical supply but does not require an overnight hospital stay. This includes a situation in which the supply is provided to the individual during a visit with a physician in an office or hospital. It may include a situation in which the individual obtains and self-administers the supply outside of the office or hospital setting, without the assistance of a home health aide or a home health agency.

Medicare and Medicaid's Coverage Standards of IBD Therapies

To identify Medicare's coverage standards for parenteral and enteral nutrition, ostomy care, medically necessary food products, and drugs approved by the FDA for the treatment of IBD in home health and outpatient delivery settings, we reviewed the standards established by the Centers for Medicare & Medicaid Services (CMS) in its national coverage policies. Specifically, we examined CMS's database of national coverage determinations (NCD) as well as its interpretive manuals, which address coverage policies. We also reviewed local coverage policies established by CMS's four Durable Medical Equipment Regional Carriers (DMERC). In addition, we reviewed relevant Medicare laws and regulations. To clarify our understanding of these materials, we interviewed CMS officials and the medical directors of the four DMERCs. We also reviewed relevant laws, and other CMS and DMERC documentation to determine if the program covers these therapies in both the home health and outpatient delivery settings.

To identify the Medicaid program's coverage standards in each state for the five therapies addressed by our study in home health and outpatient delivery settings, we sent a survey to Medicaid offices in the 50 states and the District of Columbia. The survey addressed each state's coverage policies and medical criteria that an individual must meet to receive each of the five therapies as a Medicaid benefit. Specifically, we asked states to indicate whether their program provides coverage of each of the five therapies and the criteria and conditions they have established, if applicable. In general, we used Medicare's coverage policies as a basis for the survey's coverage questions, and we provided states the opportunity to describe how their policies varied from Medicare's policies. We also provided states with the option of describing other pertinent criteria they may have established. The survey asked them to indicate whether they had different coverage policies for adults and children for such therapies. Because Medicare does not cover medically necessary food products and self-administered prescription medications, we formulated our survey questions on applicable coverage standards for these two items based on discussions with medical experts and organizations that represent IBD patients, and our review of pertinent literature. Regarding drugs used to treat IBD, we consulted with the FDA, which provided us with a list of nine brand name drugs and two generic drugs that it had approved to treat Crohn's disease and ulcerative colitis. We included these drugs in our survey.[1]

We pretested our survey with Medicaid officials in the District of Columbia, Georgia, and Virginia. We selected the District of Columbia and Georgia because of the contrasting sizes of these two Medicaid programs. We selected Virginia to obtain additional input on the structure of our questions related to prescription drug coverage. We received responses from all of the states and reviewed these data for obvious inconsistency errors and completeness. For responses that were unclear or incomplete, we contacted survey respondents to obtain clarification before conducting our analyses. We did not verify all the information we received in the survey. When necessary, we compared our electronic data files of survey responses with the actual surveys we obtained from states. We also did several internal verification checks to ensure accuracy. Based on these

[1]The nine brand name drugs listed in our survey were Asacol, Azulfidine, Canasa, Colazal, Dipentum, Entocort, Pentasa, Remicade, and Rowasa. The survey also listed the generic equivalents of two of these drugs, Azulfidine and Rowasa. After we administered our survey, the FDA informed us that it also considers several additional drugs as valid treatments for IBD. These drugs are not discussed in this report.

efforts, we determined that the data were sufficiently reliable for the purposes of this report.

To improve our understanding of how Medicare's and Medicaid's coverage standards apply to the five therapies, we also reviewed pertinent literature, interviewed two physicians who are regarded as experts in the field of gastrointestinal diseases, and convened a panel consisting of representatives of organizations that study or serve the needs of IBD patients. The following organizations participated in this panel:

- American Society for Parenteral and Enteral Nutrition
- American Gastroenterological Association
- Coram Healthcare (provider of home infusion services)
- Crohn's Disease and Colitis Foundation of America
- Digestive Disease National Coalition
- North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition
- The Oley Foundation for Home Parenteral and Enteral Nutrition
- United Ostomy Association[2]

Specific Supplies Paid for by Medicare and State Medicaid Programs

To identify the specific supplies used in the covered therapies that Medicare will pay for, we reviewed relevant NCDs, local coverage policies, and CMS interpretive manuals. We interviewed CMS officials and the four DMERC directors about the supplies that Medicare will pay for, and any applicable limitations or restrictions. To improve our understanding of the various supplies used in each therapy, we obtained information from the two medical experts and representatives of organizations that participated in our panel.

To determine the specific supplies that state Medicaid programs will pay for, we provided in our survey a list of commonly used supplies for each of the five therapies. To determine the supplies that are most commonly used in the five therapies, we interviewed the directors of the four DMERCs, representatives of some of the organizations that participated in our panel, and the two medical experts, and reviewed relevant literature. States were asked to report whether or not the specific supplies listed were covered for adults and children, and whether their Medicaid program would cover these supplies in both home health and outpatient delivery settings. In the

[2]The United Ostomy Association permanently ceased operations on September 30, 2005.

case of parenteral and enteral nutrition, and ostomy supplies, we listed items by name and included their identifying codes as specified in the Health Care Common Procedure Coding System (HCPCS).[3] Because there is no standard definition of what constitutes medically necessary food products, we developed a list of items that members of our panel and the physicians we spoke to generally considered commonly used. To determine whether states covered medications to treat IBD, we asked states to indicate whether they paid for the nine brand name drugs and two generic drugs listed in our survey. With the exception of drugs, we asked states to indicate whether they had established any restrictions, including supply limits and monetary caps, on the provision of covered products. We conducted our work from December 2004 through November 2005, in accordance with generally accepted government auditing standards.

[3]HCPCS was developed by CMS to standardize coding systems used to process Medicare claims for medical services and procedures furnished by physicians and other health care professionals, as well as other medical products, supplies, and services.

Appendix II: Reported State Medicaid Program Coverage of Therapies Used by IBD Patients

State	Parenteral nutrition	Enteral nutrition	Ostomy care	Medically necessary food products	Drugs[a]
Alabama	●	●	●	●	●
Alaska	●	●	●	●	●
Arizona	●	●	●	●	●
Arkansas[b]	●	●	●	●	●
California	●	●	●	●	●
Colorado	●	●	●	●	●
Connecticut	●	●	●	●	●
Delaware	●	●	●	●	●
District of Columbia	●	●	●	●	◉
Florida	●	●	●	●	●
Georgia	○	●	●	○	●
Hawaii	●	●	●	●	●
Idaho	●	●	●	●	●
Illinois	●	●	●	●	●
Indiana	●	●	●	●	●
Iowa	●	●	●	●	●
Kansas	●	●	●	○	●
Kentucky	●	●	●	●	●
Louisiana	●	●	●	○	●
Maine	●	●	●	●	●
Maryland	●	●	●	○	●
Massachusetts	●	●	●	●	●
Michigan	●	●	●	●	●
Minnesota	●	●	●	●	●
Mississippi	●	●	●	●	●
Missouri	●	●	●	●	●
Montana	●	●	●	○	●
Nebraska	●	●	●	●	●
Nevada	●	●	●	⊘	●
New Hampshire	●	●	●	●	●
New Jersey	●	●	●	●	●
New Mexico	●	●	●	●	●
New York	●	●	●	●	●
North Carolina	●	●	●	⊘	●
North Dakota	●	●	●	●	●

State	Parenteral nutrition	Enteral nutrition	Ostomy care	Medically necessary food products	Drugs[a]
Ohio	●	●	●	⊘	●
Oklahoma	●	○	●	○	●
Oregon	●	●	●	●	●
Pennsylvania	●	●	●	●	●
Rhode Island	●	●	●	●	●
South Carolina	●	●	●	●	●
South Dakota	●	●	●	●	●
Tennessee	●	●	●	●	●
Texas	●	●	●	●	●
Utah	●	●	●	⊘	●
Vermont	●	●	●	●	●
Virginia	●	●	●	●	●
Washington	●	●	●	●	●
West Virginia	●	⊘	●	⊘	●
Wisconsin	●	●	●	●	●
Wyoming	●	●	●	●	●

● Covered for both adults and children

◉ Covered for adults only

○ Covered for children only

⊘ State does not cover

Source: GAO survey of state Medicaid programs.

[a]For purposes of this analysis, we are defining coverage as any state that covers at least one of the brand name drugs or generic equivalent drugs listed in our survey for adults or children.

[b]Only total parenteral nutrition is covered.

Appendix III: Reported Parenteral Nutrition Therapy Coverage Standards by State Medicaid Program

State	Pathology[a]	Permanent condition[b]	Intravenous only[c]	Other therapies failed[d]	Clinical condition[e]	Documentation required[f]
Alabama	●	●	●	●	●	●
Alaska	●	●	●	●	●	●
Arizona[g]	●	⊗	⊗	⊗	⊗	●
Arkansas[h]	●	⊗	⊗	⊗	●	●
California	●	⊗	⊗	⊗	●	●
Colorado	●	⊗	⊗	●	⊗	●
Connecticut	⊗	⊗	⊗	⊗	⊗	⊗
Delaware	●	⊗	⊗	⊗	⊗	●
District of Columbia	●	⊗	⊗	●	●	●
Florida	⊗	⊗	⊗	⊗	⊗	⊗
Georgia	○	○	○	○	○	○
Hawaii[i]	●	⊗	⊗	⊗	⊗	●
Idaho	⊗	⊗	⊗	⊗	⊗	●
Illinois	●	●	●	⊗	●	●
Indiana	⊗	⊗	⊗	⊗	⊗	●
Iowa	●	●	●	⊗	●	●
Kansas	⊗	⊗	●	⊗	⊗	●
Kentucky[j]	●	⊗	⊗	⊗	●	●
Louisiana	●	●	●	●	●	●
Maine	●	●	⊗	●	●	●
Maryland	⊗	⊗	⊗	⊗	⊗	⊗
Massachusetts	●	●	●	⊗	●	●
Michigan	●	●	●	●	●	●
Minnesota	⊗	⊗	⊗	⊗	⊗	⊗
Mississippi	●	●	⊗	●	⊗	●
Missouri[k]	●	●	⊗	●	⊗	⊗
Montana[l]	●	●	⊗	⊗	⊗	●
Nebraska	●	⊗	⊗	⊗	●	⊗
Nevada	●	●	●	⊗	●	●
New Hampshire	◉	◉	◉	◉	◉	◉
New Jersey	◉	⊗	◉	◉	◉	●
New Mexico	⊗	⊗	⊗	⊗	●	●
New York	●	⊗	⊗	⊗	⊗	●
North Carolina	●	⊗	⊗	⊗	●	●
North Dakota	●	●	●	⊗	⊗	●

State	Pathology[a]	Permanent condition[b]	Intravenous only[c]	Other therapies failed[d]	Clinical condition[e]	Documentation required[f]
Ohio	●	●	⊗	●	●	●
Oklahoma	●	◉	◉	●	⊗	●
Oregon	●	⊗	⊗	⊗	●	●
Pennsylvania	⊗	⊗	⊗	⊗	⊗	●
Rhode Island	●	●	◉	◉	●	●
South Carolina	●	●	●	●	●	●
South Dakota	●	◉	◉	●	●	●
Tennessee	●	◉	◉	◉	●	●
Texas	●	●	●	●	●	●
Utah	●	⊗	●	●	⊗	●
Vermont	●	●	●	●	●	●
Virginia	⊗	⊗	◉	⊗	◉	◉
Washington	●	●	●	⊗	⊗	●
West Virginia	●	●	●	⊗	●	●
Wisconsin	●	●	●	●	⊗	●
Wyoming	●	◉	●	●	⊗	●

● Applies to both adults and children

◉ Applies to adults only

○ Applies to children only

⊗ Coverage standard or requirement does not apply

Source: GAO survey of state Medicaid programs.

[a]Patient has to have a severe pathology of the gastrointestinal tract that does not allow absorption of sufficient nutrients to maintain weight and strength.

[b]Patient has to have a permanent impairment of the gastrointestinal tract, i.e., lasting at least 3 months.

[c]The patient's maintenance of weight and strength needs to be through intravenous nutrition only.

[d]Other therapies—such as enteral nutrition and medication—need to have failed in order for the state to cover parenteral nutrition.

[e]Patient must have a specific clinical condition in order to qualify for coverage of parenteral nutrition.

[f]Specific documentation—such as proof of medical condition, duration of gastrointestinal impairment, and list of medications used—has to be provided in the patients' medical record.

[g]For acute care adults receiving total parenteral nutrition, parenteral nutrition therapy must be the sole source of nutrition.

[h]Only total parenteral nutrition is covered. Individuals must document the reason enteral feeding cannot be given.

[i]The coverage standards related to partial impairment and clinical conditions are not mandatory. A state official reported that the state generally tries to follow these standards.

[j]The coverage standards related to pathology and clinical conditions are only applicable in home health delivery settings.

[k]The recipient must require total parenteral nutrition to sustain life. Adequate nutrition must not be possible by dietary adjustment, oral supplements, or tube enteral nutrition.

[l]Parenteral nutrition therapy must be the primary source of nutrition.

Appendix IV: Reported Enteral Nutrition Therapy Coverage Standards by State Medicaid Program

State	Pathology[a]	Permanent condition[b]	Tube feeding[c]	Partial impairment[d]	Products and supplies[e]	Documentation required[f]
Alabama	○	⊗	●	⊗	○	●
Alaska	●	●	●	●	●	●
Arizona[g]	●	⊗	●	●	●	●
Arkansas[h]	◉	⊗	○	○	○	●
California	●	⊗	⊗	●	●	●
Colorado	●	⊗	●	●	●	●
Connecticut	●	⊗	●	●	●	⊗
Delaware	⊗	⊗	●	●	●	●
District of Columbia	●	●	●	●	○	●
Florida	●	⊗	◉	●	●	●
Georgia	●	●	●	●	⊗	●
Hawaii	●	◉	◉	●	●	●
Idaho	⊗	⊗	●	●	●	●
Illinois	●	⊗	⊗	●	●	●
Indiana	●	⊗	●	⊗	●	●
Iowa[i]	●	●	●	●	●	●
Kansas	◉	●	●	○	○	●
Kentucky[j]	⊗	⊗	◉	●	●	●
Louisiana[k]	⊗	●	⊗	●	●	⊗
Maine	●	●	●	●	⊗	●
Maryland	⊗	⊗	◉	⊗	⊗	●
Massachusetts	⊗	⊗	●	●	●	●
Michigan	●	⊗	●	●	●	●
Minnesota	●	⊗	⊗	●	●	●
Mississippi	◉	◉	◉	○	○	●
Missouri	⊗	⊗	⊗	⊗	◉	◉
Montana[l]	●	●	●	●	○	●
Nebraska	●	⊗	●	●	●	⊗
Nevada	●	⊗	●	●	⊗	●
New Hampshire	⊗	⊗	⊗	●	●	●
New Jersey	⊗	⊗	⊗	●	●	●
New Mexico[m]	●	⊗	●	●	●	●
New York	⊗	⊗	⊗	●	●	●
North Carolina	⊗	⊗	●	●	⊗	●
North Dakota	●	●	●	●	●	●

State	Pathology[a]	Permanent condition[b]	Tube feeding[c]	Partial impairment[d]	Products and supplies[e]	Documentation required[f]
Ohio	●	●	⊗	●	●	●
Oklahoma[n]	○	○	○	○	○	○
Oregon	●	⊗	⊗	●	●	●
Pennsylvania	⊗	⊗	⊗	⊗	●	●
Rhode Island	◉	◉	⊗	●	●	●
South Carolina[o]	●	●	●	●	●	●
South Dakota	◉	◉	◉	●	●	●
Tennessee	●	◉	●	●	●	●
Texas	●	●	●	●	●	●
Utah	●	⊗	●	⊗	⊗	●
Vermont	●	●	●	●	●	●
Virginia	●	○	●	⊗	○	●
Washington	●	⊗	⊗	●	●	●
West Virginia	⊘	⊘	⊘	⊘	⊘	⊘
Wisconsin[o]	●	⊗	●	●	●	●
Wyoming	●	◉	●	◉	⊗	●

● Applies to both adults and children

◉ Applies to adults only

○ Applies to children only

⊘ State does not cover therapy

⊗ Coverage standard or requirement does not apply

Source: GAO survey of state Medicaid programs.

[a]Patient has to have a severe pathology or non-function of the structures that normally permit food to reach the small bowel (e.g., inability to swallow), which impairs the ability to maintain weight and strength.

[b]The impairment has to be considered a permanent condition, i.e., lasting at least 3 months.

[c]The patient's condition must necessitate tube feedings to provide sufficient nutrients to maintain weight and strength (i.e., patient must be unable to obtain adequate nutrition through dietary adjustment and/or oral supplements).

[d]Enteral nutrition for patients with partial impairments (e.g., Crohn's disease patient who requires prolonged infusion of enteral nutrients to overcome an absorption problem) is possible.

[e]The state covers enteral nutrition products, and related supplies, that are administered orally.

[f]Specific documentation related to enteral nutrition therapy has to be provided in the patients' medical record.

[g]For acute care adult patients, enteral therapy must be the sole source of nutrition.

[h]For adults, enteral nutrition is covered only if it is the sole source of nutrition.

[i]For adults and children, enteral nutrition must provide 51 percent of more of caloric intake.

[j]For adults, the tube feeding criterion is only applicable in home health delivery settings.

[k]The state does not require documentation for adults. It did not respond to this question for children.

[l]Enteral nutrition therapy must be the primary source of nutrition. The state may cover oral nutritional products for children who have had an early and periodic screening, diagnostic, and treatment screening which results in a diagnosed condition that impairs absorption of specific nutrients.

[m]Documentation must indicate that there is a defined pathologic process for which nutritional support is therapeutic.

[n]The state only covers this therapy for children.

[o]Tube feeding coverage standard is to sustain life rather than to maintain weight and strength.

Appendix V: Reported Medically Necessary Food Products Coverage Standards by State Medicaid Program

State	Essential source[a]	Specific condition[b]	Hospitalization[c]
Alabama	●	●	⊗
Alaska	●	⊗	⊗
Arizona[d]	●	●	⊗
Arkansas	○	⊗	⊗
California	●	●	⊗
Colorado	●	●	⊗
Connecticut	●	●	⊗
Delaware	●	●	⊗
District of Columbia	●	⊗	⊗
Florida	●	●	⊗
Georgia	○	○	⊗
Hawaii	⊗	⊗	⊗
Idaho	●	⊗	⊗
Illinois	●	⊗	⊗
Indiana	●	⊗	⊗
Iowa	●	●	⊗
Kansas	○	⊗	⊗
Kentucky[e]	⊗	⊗	⊗
Louisiana	○	⊗	⊗
Maine	⊗	●	⊗
Maryland	⊗	○	⊗
Massachusetts	●	●	⊗
Michigan	⊗	⊗	⊗
Minnesota	●	●	⊗
Mississippi	●	●	⊗
Missouri	◉	●	⊗
Montana	⊗	○	⊗
Nebraska[f]	●	⊗	⊗
Nevada	⊘	⊘	⊘
New Hampshire	⊗	●	⊗
New Jersey	●	⊗	⊗
New Mexico[g]	⊗	●	⊗
New York	●	⊗	⊗
North Carolina	⊘	⊘	⊘
North Dakota	●	●	●

State	Essential source[a]	Specific condition[b]	Hosptalization[c]
Ohio	⊘	⊘	⊘
Oklahoma	○	⊗	⊗
Oregon	●	●	⊗
Pennsylvania	⊗	⊗	⊗
Rhode Island	◉	●	⊗
South Carolina	⊗	⊗	⊗
South Dakota[h]	◉	●	⊗
Tennessee	●	●	⊗
Texas	●	●	⊗
Utah	⊘	⊘	⊘
Vermont	●	●	⊗
Virginia	●	⊗	⊗
Washington	●	⊗	⊗
West Virginia	⊘	⊘	⊘
Wisconsin	●	●	⊗
Wyoming	⊗	⊗	⊗

● Applies to both adults and children

◉ Applies to adults only

○ Applies to children only

⊘ State does not cover therapy

⊗ Coverage standard or requirement does not apply

Source: GAO survey of state Medicaid programs.

[a]Medically necessary food products must be an essential source of nutrition.

[b]Medically necessary food products are covered only for specific conditions.

[c]Medically necessary food products are covered only during the period following hospitalization.

[d]For acute care adult patients, medically necessary food products must be the sole source of nutrition.

[e]The state covers medically necessary food products for certain inherited metabolic diseases.

[f]The state covers medically necessary food products if products are necessary to provide sufficient nutrients to maintain weight and strength commensurate with patient's overall health status.

[g]To receive coverage, a patient must have a defined and specific pathologic condition for which nutritional support is therapeutic. If the purpose is simply to provide food, then it is not considered medically necessary.

[h]Nutritional therapy must be the sole source of nutrition.

Appendix VI: Reported Parenteral Nutrition Supplies Covered by Medicaid in Home Health and Outpatient Delivery Settings

State	Parenteral nutrition[a]	Parenteral nutrition supply kit[b]	Parenteral nutrition administration kit	Parenteral nutrition infusion pump[c]	Intravenous pole
Alabama	⊘	◉	◉	●	●
Alaska	●	●	●	●	●
Arizona	●	●	●	●	●
Arkansas[d]	●	●	●	●	●
California	●	⊘	●	●	●
Colorado	⊘	●	●	●	●
Connecticut	●	●	●	●	●
Delaware	⊘	⊘	⊘	●	●
District of Columbia	●	●	●	●	●
Florida	●	⊘	⊘	⊘	○
Georgia	○	●	●	●	●
Hawaii	●	●	●	●	⊘
Idaho	●	●	●	●	●
Illinois	●	●	●	●	●
Indiana	●	●	●	●	●
Iowa	●	●	●	●	●
Kansas	●	●	●	●	●
Kentucky	●	●	●	●	●
Louisiana	●	●	●	●	●
Maine	●	●	●	●	●
Maryland	⊘	●	●	●	●
Massachusetts	●	●	●	●	●
Michigan	⊘	●	●	●	●
Minnesota	⊘	●	●	●	●
Mississippi	●	●	●	●	●
Missouri	●	●	●	●	●
Montana	●	●	●	●	●
Nebraska	●	●	●	●	●
Nevada	●	●	●	●	●
New Hampshire	●	●	●	●	●
New Jersey	●	●	●	●	●
New Mexico	●	●	●	●	●
New York	●	●	●	●	●
North Carolina	●	●	●	●	●
North Dakota	●	●	●	●	●

State	Parenteral nutrition[a]	Parenteral nutrition supply kit[b]	Parenteral nutrition administration kit	Parenteral nutrition infusion pump[c]	Intravenous pole
Ohio	⊘	⊘	⊘	●	●
Oklahoma	●	●	●	●	●
Oregon	●	●	●	●	●
Pennsylvania	●	●	●	⊘	●
Rhode Island	●	●	●	●	●
South Carolina	●	●	●	●	●
South Dakota	●	●	●	●	●
Tennessee	●	●	●	●	●
Texas	○	○	○	●	○
Utah	●	⊘	●	●	●
Vermont	●	●	●	●	●
Virginia	●	●	●	●	●
Washington	●	●	●	●	●
West Virginia	●	●	●	●	●
Wisconsin	●	●	●	●	●
Wyoming	●	●	●	●	●

● Covered for both adults and children
◉ Covered for adults only
○ Covered for children only
⊘ State does not cover supply

Outpatient settings
Home health setting
Home health and outpatient settings

Source: GAO survey of state Medicaid programs.

[a]Parenteral nutrition solution includes all types of solutions.

[b]Parenteral nutrition supply kit which can be premixed or mixed at home.

[c]Parenteral nutrition infusion pump can be portable or stationary.

[d]Supplies are covered only when administered at home. They are not covered in other outpatient delivery settings.

Appendix VII: Reported Enteral Nutrition Supplies Covered by Medicaid in Home Health and Outpatient Delivery Settings

State	Enteral formula[a]	Enteral feeding supply kit[b]	Tubing[c]	Additive[d]	Infusion pump[e]	Intravenous pole	Catheter[f]
Alabama	●	○	●	☒	●	●	○
Alaska	●	●	●	●	●	●	●
Arizona	●	●	●	●	●	●	●
Arkansas[g]	●	●	●	⊘	●	●	●
California	●	●	●	●	●	●	⊘
Colorado	●	●	●	●	●	●	●
Connecticut	●	●	●	⊘	●	●	⊘
Delaware	●	●	●	●	●	●	●
District of Columbia	●	●	●	●	●	●	◉ ○
Florida	○	○	○	○	○	○	○
Georgia	○	●	●	⊘	●	●	●
Hawaii	●	●	●	●	●	●	●
Idaho	◉ ○	●	●	●	●	●	⊘
Illinois[h]	●	●	●	●	●	●	●
Indiana	●	●	●	⊘	●	●	●
Iowa	●	●	●	⊘	●	●	●
Kansas	●	●	●	●	●	●	●
Kentucky	●	●	●	●	●	●	●
Louisiana	⊘	●	●	⊘	●	●	⊘
Maine[i]	●	●	●	⊘	●	●	●
Maryland	⊘	●	●	⊘	⊘	⊘	⊘
Massachusetts	●	●	●	●	●	●	●
Michigan	●	●	●	⊘	●	●	●
Minnesota	●	⊘	●	⊘	●	●	●
Mississippi	●	●	●	⊘	●	●	⊘
Missouri[j]	●	●	●	●	●	⊘	◉ ○
Montana	●	●	●	●	●	●	●
Nebraska	●	●	●	●	●	●	●
Nevada	●	●	●	●	●	●	●
New Hampshire	●	●	●	●	●	●	●
New Jersey	●	●	●	●	●	●	●
New Mexico	●	●	●	●	●	●	●
New York	●	●	●	⊘	●	●	●
North Carolina	●	●	◉ ○	⊘	●	●	⊘
North Dakota	●	●	●	●	●	●	●

State	Enteral formula[a]	Enteral feeding supply kit[b]	Tubing[c]	Additive[d]	Infusion pump[e]	Intravenous pole	Catheter[f]
Ohio	⊘	●	●	⊘	●	●	⊘
Oklahoma	○	○	○	○	○	○	○
Oregon	●	●	●	●	●	●	●
Pennsylvania[k]	●	●	●	⊘	●	●	●
Rhode Island	●	●	●	●	●	●	●
South Carolina	●	●	●	●	●	●	●
South Dakota[l]	●	●	●	●	●	●	●
Tennessee	●	●	●	●	●	●	●
Texas	●	●	●	●	●	○	●
Utah	●	●	⊘	⊘	●	●	⊘
Vermont	●	●	●	●	●	●	●
Virginia	●	●	●	⊘	●	●	●
Washington	⊘	●	●	⊘	●	●	⊘
West Virginia	⊗	⊗	⊗	⊗	⊗	⊗	⊗
Wisconsin[m]	●	●	●	⊘	●	●	●
Wyoming	●	●	●	●	⊘	●	⊘

● Covered for both adults and children
◉ Covered for adults only
○ Covered for children only
⊘ State does not cover supply
⊗ State does not cover therapy
Outpatient settings
Home health setting
Home health and outpatient settings
☒ No response

Source: GAO survey of state Medicaid programs.

[a]Enteral formula includes all types.

[b]Enteral feeding supply kit includes the syringe, pump, and gravity fed.

[c]Tubing includes all types including nasogastric, stomach, and gastrostomy.

[d]Additives for enteral formula.

[e]Enteral nutrition includes infusion pump with or without an alarm.

[f]Catheter includes percutaneous catheter, tube anchoring device and adhesive skin attachment.

[g]State's coverage is limited to home health delivery settings.

[h]The state does not cover enteral nutrition infusion pump – without alarm.

[i]The state does not cover blenderized enteral formulas.

[j]For adults, the state handles coverage for enteral supplies on a case-by-case basis.

[k]The state only covers specific enteral nutrition supplies. Nasogastric tubings with and without stylets along with stomach tubes are only covered for children.

[l]Pediatric enteral formula and blenderized enteral formula are only covered for children under the age of 21.

[m]The state does not cover all enteral formulas.

Appendix VIII: Reported Percent of States Covering Ostomy Supplies in Home Health and Outpatient Delivery Settings

Supply[a] name	Home health delivery setting	Outpatient delivery setting
Drainable pouch with extended wear barrier		
Ostomy pouch, drainable, with extended wear barrier attached	84	88
Ostomy pouch, drainable, with extended wear barrier attached, with built-in convexity	84	88
Drainable pouch – standard barrier		
Ostomy pouch, drainable with faceplate attached, plastic	84	90
Ostomy pouch, drainable with faceplate attached, rubber	84	90
Ostomy pouch, drainable, for use on faceplate, plastic	84	90
Ostomy pouch, drainable, for use on faceplate, rubber	84	86
Ostomy pouch, drainable, with barrier	84	88
Ostomy pouch, drainable, high output, for use on a barrier with flange (2 piece system), with filter	80	82
Ostomy pouch, closed, for use on barrier with locking flange, with filter (2 pieces)	80	84
Ostomy pouch, drainable, with barrier attached, with filter (1 piece)	80	84
Ostomy pouch, drainable, for use on barrier with non-locking flange, with filter (2 pieces)	80	84
Ostomy pouch, drainable, for use on barrier with locking flange (2 pieces)	80	84
Ostomy pouch, drainable, for use on barrier with locking flange, with filter (2 pieces)	78	82
Ostomy pouch, drainable, without barrier attached (1 piece)	86	84
Ostomy pouch, drainable with barrier attached (1 piece)	88	88
Ostomy pouch, drainable, for use on barrier with flange (2 piece system)	90	90
Irrigation supply		
Irrigation supply; sleeve	82	86
Ostomy irrigation supply; bag	78	82
Ostomy irrigation supply; cone/catheter, including brush	80	86
Lubricant	82	84
Continent device, plug for continent stoma	82	84
Continent device, catheter for continent stoma	82	84
Fluid discharge management		
Bedside drainage bottle	75	75
Barrier with adhering pouch		
Ostomy barrier, with flange, with built-in convexity	84	92
Ostomy skin barrier, with flange, without built-in convexity, 4x4 inches or smaller	86	88
Barrier – extended wear		
Ostomy skin barrier, solid 4x4 inches, extended wear, without built-in convexity	84	88
Ostomy skin barrier, with flange, extended wear, with built-in convexity, 4x4 inches or smaller	88	88

Supply[a] name	Home health delivery setting	Outpatient delivery setting
Ostomy skin barrier, with flange, extended wear with built-in convexity, larger than 4x4 inches	84	86
Ostomy skin barrier, with flange, extended wear, without built-in convexity, 4x4 inches or smaller	84	86
Ostomy skin barrier, with flange, extended wear, without built-in convexity, larger than 4x4 inches	84	86
Barrier skin protection		
Skin barrier, solid; 4x4 inches	86	92
Adhesive, liquid	90	92
Ostomy skin barrier, liquid	88	94
Ostomy skin barrier, powder	88	94
Ostomy barrier, solid	84	90
Ostomy faceplate equivalent, silicone ring	82	86
Ostomy ring	88	92
Ostomy skin barrier, non-pectin based, paste	86	88
Ostomy skin barrier, pectin-based paste	86	84
Skin barrier, wipes, box of 50	86	86
Skin barrier, solid, 6x6 inches	88	86
Skin barrier, solid, 8x8 inches	86	86
Adhesive or non-adhesive, disk or foam pad	86	86
Closed pouch		
Ostomy skin barrier, closed, with extended wear barrier attached, with built-in convexity	84	88
Ostomy pouch, closed, with barrier, with filter	80	84
Ostomy pouch, closed, with barrier attached, with built-in convexity	80	84
Ostomy pouch, closed, without barrier, with filter (1 piece)	80	84
Ostomy pouch, closed, fuse use on barrier with non-locking flange (2 pieces)	78	82
Ostomy pouch, closed, fuse use on barrier with locking flange (2 pieces)	77	80
Ostomy pouch, closed, with barrier attached	88	92
Ostomy pouch, closed, without barrier attached	90	90
Ostomy pouch, closed, for use on faceplate	86	90
Ostomy pouch, closed, for use on barrier with flange	90	92
Stoma cap	86	92
Other accessories		
Ostomy faceplate	84	88
Adhesive remover wipes	82	80
Ostomy vent	73	80
Ostomy belt	88	92

Appendix VIII: Reported Percent of States Covering Ostomy Supplies in Home Health and Outpatient Delivery Settings

Supply[a] name	Home health delivery setting	Outpatient delivery setting
Ostomy belt with peristomal hernia support	75	80
Ostomy filter	75	82
Ostomy deodorant, liquid	73	78
Ostomy deodorant, solid	73	77
Ostomy supply, miscellaneous	80	84
Ostomy absorbent material for use in ostomy pouch to thicken liquid stomal output	73	75
Tape, non-waterproof	88	86
Tape, waterproof	88	86
Adhesive remover or solvent	86	90
Ostomy accessory, convex insert	82	84
Appliance cleaner, incontinence and ostomy appliances	75	77

Source: GAO survey of state Medicaid programs.

[a]Ostomy supplies were placed in related categories based on discussions with an official from the United Ostomy Association.

Appendix IX: Reported Information on Medicaid Coverage of Ostomy Supplies and Related Limits

State	Number of supplies covered		Percent of covered supplies with dollar caps and/or supply limits	Percent of dollar caps or supply limits that are exceeded:			
	Home health	Outpatient		Often	Rarely	Never	No response
Alabama	14	8	20	0	0	100	0
Alaska	69	69	81	0	100	0	0
Arizona	69	69	100	26	23	51	0
Arkansas[a]	54	54	78	0	0	100	0
California	60	59	15	90	0	0	10
Colorado	69	69	0	0	0	0	0
Connecticut	64	0	93	0	98	0	2
Delaware	69	69	96	0	100	0	0
District of Columbia	0	69	100	55	38	7	0
Florida	65	66	96	0	99	0	2
Georgia	0	17	25	0	100	0	0
Hawaii	69	69	100	100	0	0	0
Idaho[b]	69	69	100	0	44	57	0
Illinois	0	68	99	2	99	0	0
Indiana	69	69	0	0	0	0	0
Iowa	69	69	96	0	99	2	0
Kansas	57	57	83	0	0	100	0
Kentucky[c]	69	68	55	100	0	0	0
Louisiana	63	63	65	0	100	0	0
Maine	69	69	0	0	0	0	0
Maryland	69	69	0	0	0	0	0
Massachusetts	67	55	97	0	100	0	0
Michigan	63	63	91	0	100	0	0
Minnesota	69	47	100	0	29	71	0
Mississippi	67	67	97	0	100	0	0
Missouri	69	68	46	0	100	0	0
Montana	69	69	100	0	100	0	0
Nebraska	69	69	100	0	99	0	1
Nevada[d]	69	69	42	0	100	0	0
New Hampshire	69	69	0	0	0	0	0
New Jersey	0	68	12	0	100	0	0
New Mexico	0	69	96	0	0	100	0

State	Number of supplies covered		Percent of covered supplies with dollar caps and/or supply limits	Percent of dollar caps or supply limits that are exceeded:			
	Home health	Outpatient		Often	Rarely	Never	No response
New York	69	69	0	0	0	0	0
North Carolina	23	0	0	0	0	0	0
North Dakota[e]	69	69	96	99	0	2	0
Ohio	52	52	74	0	100	0	0
Oklahoma	69	69	10	0	0	100	0
Oregon	68	68	99	0	100	0	0
Pennsylvania	57	58	45	0	100	0	0
Rhode Island	69	69	100	100	0	0	0
South Carolina	69	69	99	0	97	3	0
South Dakota	67	67	0	0	0	0	0
Tennessee	69	69	0	0	0	0	0
Texas	57	0	10	86	0	0	14
Utah	35	35	6	0	100	0	0
Vermont	69	69	0	0	0	0	0
Virginia	69	69	100	100	0	0	0
Washington	68	68	65	9	76	16	0
West Virginia	69	69	100	0	0	100	0
Wisconsin	62	62	90	0	100	0	0
Wyoming	69	69	0	0	0	0	0

Source: GAO survey of state Medicaid programs.

Note: Responses for percent of monetary caps or supply limits may exceed 100 percent due to rounding.

[a]Supplies are only covered if they are used at home. Dollar caps and supply limits only apply to adults.

[b]The state has supply limits and dollar caps that can never be exceeded for certain supplies; however some of the limits and caps are very high. For example, for one item that can never be exceeded—the ostomy belt with peristomal hernia support—the state reported that it will pay for up to 999 belts and $38,571.39 per month.

[c]There are no supply limits or dollar caps for home health ostomy supplies.

[d]Supply limits or dollar caps are only for home health.

[e]Once the accumulated dollar value of all products reaches $300 or more in a year, the state looks at the usage patterns and other information. The state reported that IBD patients often reach or exceed the $300 limit but it often allows individuals to exceed the amount with written justification.

Appendix X: Reported Medically Necessary Food Products Covered by State Medicaid Program

State	Perscription strength vitamins	Oral nutritional formulas	Food thickeners	Baby food and other blenderized products	Other products
Alabama	●	●	●	⊘	⊘
Alaska[a]	●	●	●	⊘	⊘
Arizona	●	●	⊘	⊘	⊘
Arkansas[b]	⊘	○	●	⊘	⊘
California	●	●	●	⊘	⊘
Colorado	●	●	●	⊘	⊘
Connecticut	●	●	●	⊘	⊘
Delaware	⊘	●	●	⊘	⊘
District of Columbia	●	⊘	⊘	⊘	⊘
Florida[c]	⊘	●	⊘	⊘	⊘
Georgia[d]	○	○	⊘	⊘	⊘
Hawaii	●	⊘	●	⊘	⊘
Idaho[e]	●	●	●	⊘	⊘
Illinois	●	●	●	⊘	⊘
Indiana	⊘	●	●	⊘	●
Iowa	●	●	⊘	⊘	⊘
Kansas	○	○	○	⊘	⊘
Kentucky	●	●	●	⊘	●
Louisiana	⊘	○	○	⊘	○
Maine	●	●	●	⊘	⊘
Maryland	○	○	○	⊘	○
Massachusetts	⊘	●	●	⊘	●
Michigan	○	●	⊘	⊘	⊘
Minnesota[f]	●	●	⊘	⊘	⊘
Mississippi[g]	○	●	⊘	⊘	⊘
Missouri	●	●	●	○	●
Montana	○	○	○	⊘	○
Nebraska	●	●	⊘	⊘	●
Nevada	⊘	⊘	⊘	⊘	⊘
New Hampshire	●	●	●	⊘	●
New Jersey	●	●	●	○	●
New Mexico[h]	●	●	●	⊘	●
New York	●	●	●	⊘	●
North Carolina	⊘	⊘	⊘	⊘	⊘
North Dakota[i]	⊘	●	●	⊘	⊘

State	Prescription strength vitamins	Oral nutritional formulas	Food thickeners	Baby food and other blenderized products	Other products
Ohio	⊘	⊘	⊘	⊘	⊘
Oklahoma	⊘	○	○	⊘	⊘
Oregon	●	●	⊘	⊘	⊘
Pennsylvania[j]	⊘	●	●	⊘	⊘
Rhode Island	●	●	●	⊘	○
South Carolina	●	⊘	⊘	⊘	⊘
South Dakota[k]	⊘	●	●	⊘	○
Tennessee	●	●	●	●	●
Texas	●	●	●	●	●
Utah	⊘	⊘	⊘	⊘	⊘
Vermont	●	●	●	⊘	⊘
Virginia	●	●	⊘	⊘	⊘
Washington[l]	⊘	●	●	⊘	⊘
West Virginia	⊘	⊘	⊘	⊘	⊘
Wisconsin	●	●	⊘	⊘	⊘
Wyoming	●	●	●	⊘	●

● Covered for both adults and children

◉ Covered for adults only

○ Covered for children only

⊘ State does not cover supply

Source: GAO survey of state Medicaid programs.

[a]For prescription strength vitamins, the state covers prenatal vitamins for pregnant women only. Prescription fluoride vitamins are covered for children up to eight years of age.

[b]The state only covers prenatal vitamins. Food thickeners are covered for any condition, as long as they are medically necessary.

[c]For prescription strength vitamins, the state limits coverage to prenatal vitamins, folic acid, pediatric vitamins with fluoride for children less than 13 years of age, multivitamins for dialysis patients, and iron supplements.

[d]The state covers special metabolic formulas for oral administration for children under medically necessary food products.

[e]For prescription strength vitamins, multivitamins can be covered but they must have prior authorization and meet the state's criteria for medically necessary.

[f]Coverage for prescription strength vitamins is based on documented vitamin deficiencies in the patient's medical record. Nutritional formulas taken orally must have prior authorization.

[g]CMS standard exemptions related to legend vitamins are covered. Pediatric vitamin supplements with fluoride are covered. Other pediatric legend vitamins may be covered with statement of medical necessity.

[h]The state requires a defined/specific pathologic condition for which nutritional support is therapeutic. If the purpose of the supply is simply to provide food, then it is not considered medically necessary.

[i]The state covers general nutritional supplements. Other disease specific products are not covered.

[j]For prescription strength vitamins, the state limits coverage for children less than two years of age or for prenatal use.

[k]For prescription strength vitamins, the state covers prenatal vitamins for women.

[l]The state does not cover nutritional shakes and vitamins.

Appendix XI: Summary of Drugs Listed in Our Survey to Treat IBD That Are Covered by Medicaid for Adults and Children

State	Drugs								
	Remicade	Colazal	Azulfidine		Rowasa		Asacol	Pentasa	Canasa	Dipentum	Entocort
	Brand	Brand	Brand	Generic	Brand	Generic	Brand	Brand	Brand	Brand	Brand
Alabama	●	●	●	●	●	●	●	●	○	●	○
Alaska	●	●	●	●	●	●	●	●	●	●	●
Arizona	●	●	●	●	●	●	●	●	●	●	●
Arkansas	◉	●	●	●	●	●	●	●	●	●	●
California	●	●	●	●	●	●	●	●	⊘	●	●
Colorado[a]	◉	◉	⊘	●	⊘	●	⊘	⊘	⊘	⊘	⊘
Connecticut	●	●	●	●	●	●	●	●	●	●	●
Delaware[b]	●	●	●	●	●	●	●	●	●	●	●
District of Columbia	◉	◉	◉	◉	◉	◉	◉	◉	◉	◉	◉
Florida	●	●	●	●	●	●	●	●	●	●	●
Georgia[c]	●	●	⊘	●	⊘	●	⊘	⊘	⊘	⊘	⊘
Hawaii	●	⊘	●	●	●	●	●	●	●	●	●
Idaho	●	●	●	●	●	●	●	●	●	●	●
Illinois[d]	●	●	●	●	●	●	●	●	●	●	●
Indiana	●	●	●	●	●	●	●	●	●	●	●
Iowa[e]	●	●	●	●	●	⊘	⊘	●	●	●	●
Kansas	●	●	●	●	●	●	●	●	●	●	●
Kentucky	●	●	●	●	●	●	●	●	●	●	●
Louisiana	●	●	●	●	●	●	●	●	●	●	●
Maine[f]	●	●	●	◉⊠	●	⊘	●	●	●	●	●
Maryland	●	●	●	●	●	●	●	●	●	●	●
Massachusetts	●	●	●	●	●	●	●	⊘	●	●	●
Michigan	◉	◉	●	●	◉	◉	◉	◉	◉	◉	◉
Minnesota[g]	●	●	⊘	●	●	●	●	●	●	●	●
Mississippi	◉	●	●	●	●	●	●	●	●	●	●
Missouri	●	●	⊘	●	●	●	●	●	●	●	●
Montana[h]	●	●	●	●	●	●	●	●	●	●	●
Nebraska[i]	●	●	●	●	●	●	●	●	●	●	●
Nevada[j]	◉	◉	⊘	●	⊘	◉	⊘	⊘	⊘	⊘	⊘
New Hampshire	●	●	●	●	●	●	●	●	●	●	●
New Jersey	●	●	●	●	●	●	●	●	●	●	●

State	Drugs								
	Remicade	Colazal	Azulfidine		Rowasa	Asacol	Pentasa	Canasa	Dipentum	Entocort
	Brand	Brand	Brand	Generic	Brand Generic	Brand	Brand	Brand	Brand	Brand
New Mexico	●	●	●	●	● ●	●	●	●	●	●
New York	●	●	●	●	● ●	●	●	●	●	●
North Carolina	●	●	●	●	● ●	●	●	●	●	●
North Dakota	●	●	●	●	● ●	●	●	●	●	●
Ohio[k]	●	●	●	●	● ●	●	●	●	●	●
Oklahoma[l]	●	●	●	●	● ●	●	●	●	●	●
Oregon	●	●	●	●	● ●	●	●	●	●	●
Pennsylvania	●	●	●	●	● ●	●	●	●	●	●
Rhode Island	●	●	●	●	● ●	●	●	●	●	●
South Carolina	●	●	●	●	● ●	●	●	●	●	☒ ○
South Dakota	●	●	●	●	● ●	●	●	●	●	●
Tennessee	●	●	●	●	● ●	●	●	●	●	●
Texas	●	⊘	⊘	⊘	⊘ ⊘	⊘	⊘	⊘	⊘	⊘
Utah	●	●	●	●	● ●	●	●	●	●	●
Vermont	●	◉	●	●	● ●	●	●	●	◉	◉
Virginia	●	●	●	●	● ⊘	●	●	●	●	●
Washington	●	●	●	●	● ●	●	●	●	●	●
West Virginia	◉	⊘	⊘	⊘	⊘ ⊘	⊘	⊘	⊘	⊘	⊘
Wisconsin[m]	●	●	●	⊘	● ●	●	●	☒	●	●
Wyoming	●	●	●	●	● ●	●	●	●	●	●

● Covered for both adults and children

◉ Covered for adults only

○ Covered for children only

⊘ State does not cover supply

☒ No response

Source: GAO survey of state Medicaid programs.

[a]The state requires patients to use a generic equivalent drug, if available.

[b]The state covers brand name drugs only after documentation of medical necessity is complete. The documentation has to include a summary of benefit versus risk.

[c]The state will cover brand name drugs with prior authorization when there are generic equivalent drugs available.

[d]The state does not cover Remicade, Colozal, and Entocort for children age 11 or under.

[e]The state requires prior authorization for Remicade and Asacol.

[f]The state did not indicate whether it covered the generic drug for Azulfidine for children.

[g]The state will pay for brand name drugs after demonstrating failure of generic equivalent drugs.

[h]The state will cover brand name drugs with prior authorization when there are generic equivalent drugs available.

[i]The state requires prior authorization for Remicade.

[j]The state requires patients to use a generic equivalent drug, if available.

[k]The state may require prior authorization if generic equivalent drug or therapeutic alternatives exist.

[l]The state requires prior authorization for brand name drugs when there is a generic equivalent drug available.

[m]The state will cover brand name drugs with prior authorization when there are generic equivalent drugs available.

Appendix XII: Comments from the Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: NOV 17 2005

TO: Leslie G. Aronovitz
Director, Health Care
Government Accountability Office

FROM: Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Government Accountability Office's Draft Report: *MEDICARE AND MEDICAID COVERAGE: Therapies and Supplies for Inflammatory Bowel Disease* (GAO-06-63)

Thank you for the opportunity to review and comment on the Government Accountability Office's (GAO) draft report entitled *MEDICARE AND MEDICAID COVERAGE: Therapies and Supplies for Inflammatory Bowel Disease*. The Centers for Medicare & Medicaid Services (CMS) support and applaud the GAO's efforts in examining health care access issues that affect Medicare beneficiaries and Medicaid recipients in order to ensure that they receive adequate health care to treat their inflammatory bowel disease (IBD) condition. The draft report states that IBD advocates have expressed concern about the ability of Medicare beneficiaries and Medicaid recipients to obtain access to IBD-related care, which has led the GAO to examine this matter.

With regard to the portions of the report that refer to the IBD therapies and supplies currently covered under Part B of the Medicare program, we have determined that the GAO has correctly described the Medicare coverage policies for parenteral nutrition, enteral nutrition, and ostomy supplies.

The CMS has the following comment to make concerning Medicare's coverage policy for the Food and Drug Administration (FDA) approved self-administered drugs:

> On page 18, in the first full paragraph, the draft report states "Medicare does not generally cover medications that are self-administered, including drugs approved by the FDA to treat IBD. Coverage is not provided because such medications are not included in any of the benefit categories contained in the Social Security Act." The reason for non-coverage, rather, should be because while the law does include a benefit category for

drugs, the benefit category limits coverage to those drugs that are usually *not* self-administered. Specifically, section 1861(s)(2)(A) of the Social Security Act which states that "services and supplies (including drugs and biologicals which are not usually self-administered by the patient) [are] furnished as an incident to a physician's professional service." This means that although IBD-related self-administered drugs are not covered by Medicare in the patient's home, IBD-related drugs could be covered by Medicare when administered by a physician in a clinical setting. We suggest that the GAO clarify this statutory limitation throughout the document where they discuss Medicare's lack of coverage. The current language implies Medicare has the authority to alter its interpretation of the law to cover FDA-approved drugs.

It is important to know why Medicare does not generally cover self-administered drugs, Medicare is currently operating a demonstration that began in September 2004 and will end on December 31, 2005. This demonstration, mandated under section 641 of the Medicare Modernization Act of 2003, serves as a bridge until the Medicare Part D benefit becomes available and covers a limited number of self-administered drugs which can replace the need for drugs covered under Medicare Part B.

We appreciate the effort that went into this report and as CMS proceeds with policy development, we will continue to give deep consideration to access issues that affect Medicare beneficiaries and Medicaid recipients in their treatment of IBD.

Appendix XIII: GAO Contact and Staff Acknowledgments

GAO Contact

Leslie G. Aronovitz (312) 220-7600 or aronovitzl@gao.gov

Staff Acknowledgments

In addition to the contact named above, Geraldine Redican-Bigott, Assistant Director; Shaunessye Curry; Adrienne Griffin; Ba Lin; Janet Rosenblad; and Pauline Seretakis made key contributions to this report.

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