# **Medical Supplies**

Page updated: August 2021

This section contains information about medical supplies, lists of products and program coverage (*Welfare & Institutions Code* [W&I Code], Section 14105.47). The information provided in this section applies to the medical supplies included on the lists below.

The following spreadsheet contains the list of covered medical supply billing codes, units, quantity limits and maximum allowable product cost (MAPC):

• Medical Supplies Billing Codes, Units and Quantity Limits

«Specific medical supplies are pharmacy provider billing only on a pharmacy claim. Specific supplies and billing codes in the *Medical Supplies Billing Codes, Units and Quantity Limits* spreadsheet are restricted to items on the following medical supply lists.»

- List of Contracted Diabetic Test Strips and Lancets
- <u>List of Contracted Intermittent Urinary Catheters</u>
- <u>List of Contracted Pen Needles</u> Effective for dates of service on or after January 1, 2021.
- <u>List of Covered Sterile Needles (HCPCS A4215 Excluding Pen Needles)</u> Effective for Dates of Service on or after January 1, 2021
- <u>List of Contracted Sterile Needles (HCPCS A4215)</u> Effective for Dates of Service Prior to January 1, 2021.
- List of Contracted Tracheostomy Supplies
- List of Contracted Wound Care Advanced Dressings
  - Effective for dates of service on or after April 1, 2020, wound care advanced dressings are no longer contracted.
- List of Contracted Waterproof Sheeting

### **Program Coverage**

Medi-Cal covers certain medical supplies when provided on the written prescription of a physician. A recipient's need for medical supplies must be reviewed by a physician annually.

## **Eligibility Requirements**

To receive reimbursement, a recipient must be eligible for Medi-Cal on the date of service. Providers should verify a recipient's eligibility for the month of service before dispensing medical supplies. Claims received for services rendered to ineligible recipients will be denied.

### **Medi-Cal Managed Care Plans**

«Except for specific medical supplies billed on a pharmacy claim,» beneficiaries enrolled in Medi-Cal Managed Care Plans (MCPs) must receive Medi-Cal medical supply benefit from plan providers. MCPs are required to provide or arrange for medically necessary medical supply products as a covered Medi-Cal benefit. Each MCP is unique in its billing and service procedures. Providers must contact the individual MCP for billing instructions.

#### **Outpatient Hemodialysis**

Medical supplies for chronic outpatient hemodialysis provided in renal dialysis centers and community hemodialysis units or for home dialysis are included in the all-inclusive rate (*California Code of Regulations* [CCR], Title 22, Section 51509.02) paid to the center or unit and are not separately reimbursable.

### **Nursing Facilities**

Medical supplies provided to inpatients receiving Nursing Facility Level A (NF-A) services or Nursing Facility Level B (NF-B) services, whether or not rendered in a hospital setting (CCR, Title 22, Sections 51510 and 51511), are reimbursable only for the medical supplies listed below and only when required by a specific patient for that patient's exclusive use.

- · Diabetic test strips and lancets
- Condoms
- Diaphragm
- Infusion Supplies heparin and saline flush and HCPCS codes A4223, A4226, A4230 thru A4232, A4305, A4306, B9999 and S1015

## **Nursing Facilities: Supplies Limited Use**

Medi-Cal separately reimbursed medical supplies are the property of the Medi-Cal recipient and are not to be shared with other recipients. Items must be labeled at least with the patient's name and physically separated from other patients' property to avoid mixing. When the recipient leaves a facility, the Medi-Cal reimbursed items must be sent with them.

## **Inpatient Hospital Services**

Medical supplies provided to inpatients receiving inpatient hospital services are included in the hospital's reimbursement made under CCR, Title 22, Section 51536. These services are not separately reimbursable.

## **Supplies for Rented DME**

Medical supplies used in the operation of rented Durable Medical Equipment (DME) are not separately billable if included in the daily rate (per diem) of the rented DME. Providers may refer to the *Durable Medical Equipment (DME): An Overview* section of this manual.

## Non-Coverage

The following are not covered under the Medi-Cal program (*California Code of Regulations*, Title 22, Sections 51320 [b] and 51313.3 [3]).

- Common household items including, but not limited to adhesive tape (all types), alcohol (rubbing, 70 percent or less), cosmetics, cotton balls and swabs, Q-tips, dusting powders, tissue wipes and witch hazel
- Common household remedies including but not limited to white petrolatum, dry skin
  oils and lotions, talc and talc combination products, oxidizing agents such as hydrogen
  peroxide, carbamide peroxide and sodium perborate and non-prescription shampoos
- Topical preparations that contain benzoic and salicylic acid ointment, salicylic acid cream, ointment or liquid and zinc oxide paste
- Other items not generally used primarily for health care and which are regularly and primarily used by persons who do not have a specific medical need for them

## **Other Health Coverage Documentation**

Medical supply providers do not need to submit a copy of Other Health Coverage (OHC) denial with <u>every</u> claim. After submitting an initial claim that establishes proof that OHC does not cover that supply, medical supply providers may submit claims for that supply for the same recipient without proof of OHC denial for a period of one year. Additional information includes:

- The one-year period begins on the date of the explanation of benefits (EOB), denial letter or dated statement of non-covered benefits.
- OHC denial claims history is billing-code specific. Providers must submit an OHC denial for each billing code; however, providers can submit claims using the same EOB, denial letter or dated statement of non-covered benefits only when it clearly states all medical supplies are not a covered benefit.
- The one-year documentation exemption does not apply to recipients who change to a
  different OHC carrier during the year. Providers should check recipients' OHC status
  at each visit. If a recipient changes to a different OHC, a new EOB, denial letter or
  dated statement of non-covered benefits is required from the new carrier.

Refer to the *Other Health Coverage* (OHC) section of this manual for additional OHC billing information.

## **Self-Certification for Other Health Coverage**

The ability to self-certify for Other Health Coverage on pharmacy claims does not apply to medical supplies, with the exception of diabetic supplies.

## **Medicare Covered Services**

Medicare covers some medical supplies. When Medicare covers an item and the recipient is eligible for Medicare, providers bill Medicare before billing Medi-Cal.

The products and product categories listed below must be billed to Medicare before being billed to Medi-Cal:

- Diabetic testing supplies (lancets, test strips and reagent tablets)
- Enteral feeding supplies
- Insulin syringes
- Ostomy supplies
- Perianal fecal collection pouch with adhesive (HCPCS code A4330)
- Tracheostomy supplies
- Urological supplies

For infusion supplies, wound care and other miscellaneous medical supplies, providers may bill Medi-Cal directly only if dispensed for a Medicare non-covered treatment. Refer to the *Medicare Non-Covered Services: HCPCS Codes* manual section in the appropriate Part 2 manual for more information.

Providers should contact the Medicare carrier for coverage and billing instructions.

## **Provider Requirements: Dangerous Medical Devices**

Regulations have been adopted to implement the provisions of *Business and Professions Code* (B&P Code), Section 4059.5. This statute requires that providers dispensing dangerous medical devices obtain a permit from the Board of Pharmacy. Dangerous medical devices, as defined in B&P Code, Section 4023 include but are not limited to hypodermic syringes and needles and devices which bear the warning: "Caution, federal law prohibits dispensing without a prescription" or similar wording.

Any Medi-Cal provider other than a licensed Pharmacy that dispenses dangerous medical devices is required to obtain a permit from the Board of Pharmacy. Failure to obtain a permit from the Board of Pharmacy or the suspension of a permit by the Board of Pharmacy is grounds for suspension of participation in the Medi-Cal program.

To obtain a permit, providers can contact the California State Board of Pharmacy at the following address:

1625 N. Market Blvd., N219 Sacramento, CA 95834-1924 Phone (916) 574-7900 Fax (916) 574-8618

## **Contracted Medical Supplies**

The Department of Health Care Services (DHCS), pursuant to W&I Code, Section 14105.3(b), has negotiated non-exclusive contracts for a maximum acquisition cost (MAC) with interested distributors, manufacturers and relabelers (contractors) for certain medical supplies. (For additional MAC information refer to "Reimbursement" elsewhere in this section.) The contractors have guaranteed that Medi-Cal providers can purchase, upon request for dispensing to eligible Medi-Cal fee-for-service recipients, the contracted product(s) at or below the MAC.

Certain medical supply HCPCS codes and diabetic testing supplies are contracted and only products in the appropriate contracted products spreadsheet are eligible for reimbursement. Items contracted for certain medical supply types are listed with a Universal Product Number (UPN).

Listing of contracted products does not guarantee the product's availability.

## **Non-Contracted Medical Supplies**

Any manufacturer's product that meets the description for non-contracted HCPCS billing codes in the *List of Medical Supplies: Billing Codes, Units and Quantity Limits* spreadsheet may be reimbursable. The non-contracted billing codes are not restricted to a list of contracted products.

«Note: Specific billing codes may be non-contracted and subject to a product list.»

## **Prescription Requirements**

A written prescription (or electronic equivalent), signed and dated by the recipient's physician, is required, ordering only those supplies necessary for the care of the recipient and as documented in the recipient's medical record.

The prescription must be dated within 12 months of the date of service on the claim.

In addition to the physician's signature and date prescribed, the following specific information must be supplied clearly on the prescription form.

- Recipient's name
- Full name, address and telephone number of the prescribing physician, if not pre-printed on the prescription form
- Product name or description of the medical supply item being prescribed
- Frequency of use
- Quantity to be dispensed

Provider records must document the diagnostic, clinical condition or requirement that fulfills the Code I restriction (refer to Code I in this section).

Page updated: August 2021

## **Authorization Requirements**

An approved *Treatment Authorization Request* (TAR) or Service Authorization Request (SAR) is required for claims using certain medical supplies billing codes and claims billing quantities in excess of the quantity limitations. Refer to the *Medical Supplies Billing Codes*, *Units and Quantity Limits* spreadsheet.

The product name on an approved TAR or product-specific SAR using miscellaneous HCPCS billing codes A4421, B9999, S8189 or T5999 must be identical to the product name dispensed and on the claim submitted for reimbursement. In the event a TAR/SAR is erroneously approved for a non-benefit item, payment for the claim will be denied.

Refer to the TAR Completion section of this manual for additional TAR information. Refer to the *California Children's Services (CCS) Program Service Authorization Request (SAR)* section of this manual for instructions for submitting a SAR or contact a CCS program/Genetically Handicapped Persons (GHPP) representative.

#### Code I

Authorization is required if the recipient does not meet the Code I restriction. Refer to the Billing Notes in the *Medical Supplies Billing Codes, Units and Quantity Limits* spreadsheet for the specific Code I clinical conditions or requirements. Pursuant to CCR, Title 22, Section 51476(c), the dispenser (provider) shall maintain readily retrievable documentation of the recipient's diagnostic or clinical condition information that fulfills the Code I restriction as documented in the recipient's medical record.

Page updated: August 2021

### **Quantity Limitations**

The quantity limitations for medical supply products are in the *Medical Supplies Billing Codes, Units and Quantity Limits* spreadsheet. TARs are required for claims billing for quantities in excess of the quantity limitations.

### **Diabetic Lancets and Test Strips**

Diabetic lancets and test strips (glucose and ketones) are Code I items, restricted to recipients being treated by a physician for a diabetes diagnosis documented in their medical records. As a Code I requirement, when billing for lancets and test strips, the following must be documented on the physician's order:

- A description of the item prescribed
- The specific frequency of testing ("as needed" or "PRN" are not acceptable)
- For a recipient currently being treated with insulin injections, document that the recipient is an insulin user

Claims billed with or without authorization for Medi-Cal reimbursement are restricted to the products in the *List of Contracted Diabetic Test Strips and Lancets* spreadsheet. These items must be billed by Pharmacy providers using National Council for Prescription Drug Programs (NCPDP) format or the *Pharmacy Claim Form* (30-1).

When billing for test strips or lancets, claim quantities must be appropriate for the product quantity/package size (for example, 10, 25, 50, 100, 150 or 200) dispensed and are limited as follows:

- For a diabetic recipient who is currently being treated with insulin injections, no more than 150 blood glucose test strips and no more than 200 lancets are allowed per claim, with no more than three (3) claims in a 90-day period
- For a diabetic recipient who is not currently being treated with insulin injections, no more than 100 blood glucose test strips and no more than 100 lancets in a 90-day period

- For a gestational diabetic recipient being treated with or without insulin injections, no more than 150 blood glucose test strips and no more than 200 lancets are allowed per claim, with no more than three (3) claims in a 90-day period
- Blood ketone test strips no more than 10 strips per claim, with no more than three (3) claims in a 90-day period
- Urine ketone and ketone/glucose test strips no more than 50 per claim, with no more than four (4) claims in a 365-day period

A TAR documenting the following is required if the recipient requires a quantity of lancets or test strips that exceeds the quantity limits:

- The recipient has nearly exhausted the supply of test strips and lancets
- A specific narrative statement, as documented in the recipient's medical record, which supports the need for testing frequency that exceeds the billing limitations
- The recipient was seen and evaluated by the treating physician for diabetes control within six months prior to ordering quantities that exceed the quantity limits

**Note:** To receive reimbursement for diabetic test strips and lancets, the product number (an 11-digit number, also referred to as the National Drug Code [NDC] or UPN) on each package (box) dispensed must be an exact match to a product billing code in the List of Contracted Diabetic Test Strips and Lancets spreadsheet and the billing code on the claim.

### **«Disposable Intravenous Pumps**

Disposable intravenous pumps, such as the Intermate and the Home Pump, are medical supplies that are potentially reimbursable by Medi-Cal subject to authorization. Disposable pumps may be approved when medically necessary and represent the least costly method that will fulfill the needed purpose.

Providers should submit *Treatment Authorization Requests* (TARs) for disposable pumps to the TAR Processing Center. When asking for authorization for a disposable pump, please address the following questions on the TAR:

- Is a pump medically necessary? Is this a drug that could be administered without a pump?
- Assuming a pump is medically necessary, why is a disposable pump needed? Could a less-expensive pump be used to administer the drug? (Examples of alternative pumps might include gravity controllers, pole-type pumps or syringe pumps.) If not, why not?>>

«Disposable intravenous pumps must be billed using medical supply HCPCS codes A4305 or A4306 (disposable drug delivery system). Refer to the Medical Supplies Billing Codes, Units and Quantity Limits spreadsheet.

**Note:** Providers should not bill disposable pumps as "containers," intravenous administration sets or hypodermoclysis sets. Examiners are instructed to deny payment for disposable pumps billed as containers or administration sets. Non-disposable intravenous pumps require authorization from a local Medi-Cal field office and must be billed as Durable Medical Equipment (DME).>>

### **Enteral Feeding Supply**

HCPCS code B4105 (in-line cartridge containing digestive enzyme(s) for enteral feeding, each) is reimbursable with an approved *Treatment Authorization Request* (TAR) or Service Authorization Request (SAR) for recipients with cystic fibrosis and exocrine pancreatic insufficiency diagnosis that meet all the conditions listed below.

Documentation must be on the TAR or SAR to support that the recipient meets all of the following conditions, as documented in the recipient's medical record:

- Be 5 years of age or older and have a clinical diagnosis of cystic fibrosis and exocrine pancreatic insufficiency (ICD-10-CM diagnosis code K86.81).
- Have a prescription for an in-line cartridge containing digestive enzyme(s), signed by a board-certified pulmonologist.
- Have their care followed by a board-certified pulmonologist at a cystic fibrosis special care center.
- Adhere to a nutritional treatment plan. Document nutritional treatment plan.
- Receive overnight enteral nutrition supplementation. Document enteral nutrition product name, type and usage.
- Have weight, height and Body Mass Index (BMI) value determined and documented within 30 days of the request.
- Have a BMI percentile less than 50 and meet one of the following:
  - The recipient is under 21 years of age with a BMI percentile less than 50 despite three or more months of overnight enteral nutrition supplementation and pancreatic enzyme replacement therapy (PERT) or other treatment modalities if PERT is contraindicated.
  - The recipient is 21 years of age or older with a BMI percentile less than 50 despite six or more months of overnight enteral nutrition supplementation and PERT or had prior use with in-line cartridge containing digestive enzyme(s) due to a BMI percentile less than 50.

- HCPCS code B4105 should be used only with enteral nutrition formula products that have been evaluated or are compatible with the in-line cartridge containing digestive enzyme(s).
- HCPCS code B4105 should be used only with enteral feeding pump systems compatible with the in-line cartridge containing digestive enzyme(s).

Authorizations for in-line cartridge containing digestive enzyme(s), HCPCS code B4105, are limited to no more than two enzyme cartridges per day for up to three months.

Reauthorization requests for HCPCS code B4105 must include supporting documentation that all of the above conditions are met and the recipient's BMI has stabilized or improved.

### Reimbursement

Medical supply reimbursement guidelines are as follows:

#### **Upper Billing Limit**

Pursuant to CCR, Title 22, Section 51008.1, claims submitted for disposable medical supplies shall not exceed an amount that is the lesser of:

- The usual charges made to the general public, or
- The net purchase price of the item, which must be documented in the provider's books and records (including all discounts and rebates), plus no more than 100 percent markup. Documentation shall include, but is not limited to, evidence of purchase such as invoices or receipts.
  - Net purchase price is defined as the actual cost to the provider to purchase the item from the seller, including refunds, rebates, discounts or any other price reducing allowances, known by the provider at the time of billing the Medi-Cal program for the item, that reduce the item's invoice amount.
  - The net purchase price shall reflect price reductions guaranteed by any contract to be applied to the item(s) billed to the Medi-Cal program.
  - The net purchase price shall not include provider costs associated with late payment penalties, interest, inventory costs, taxes, or labor.
- Providers shall not submit bills for items obtained at no cost.

Page updated: August 2021

#### **Maximum Reimbursement**

The maximum amount reimbursed to providers will be the lesser of:

- The usual charges made to the general public, or
- The net purchase price of the item (including all discounts and rebates), plus no more than 100 percent markup, or
- The MAPC (price on file) or the documented cost ("By Report") for the item, plus the 23 percent dealer markup and tax (if applicable)

**Note:** The maximum reimbursement is the MAPC (price on file) for the item plus the appropriate professional dispensing fee.

### **Maximum Allowable Product Cost (MAPC)**

The maximum allowable product cost (MAPC) established by DHCS, pursuant to W&I Code, Section 14105.47 is the maximum product cost reimbursed (price on file).

### **Maximum Acquisition Cost (MAC)**

The manufacturer, relabeler or distributor has guaranteed that Medi-Cal providers, upon request, will be able to purchase the contracted item at no greater than the maximum acquisition cost (MAC) for dispensing to eligible Medi-Cal fee-for-service recipients.

**Note:** The MAPC and MAC are the same for certain contracted medical supplies.

#### Sales Tax

Sales tax on taxable items, such as medical supplies, is included in the Medi-Cal reimbursement. After the Medi-Cal allowable amount is computed, sales tax, at rates appropriate to the county, is added to the reimbursement. The determination of which items are taxable is made in accordance with Board of Equalization rules.

Providers should include sales tax on Medi-Cal claims for taxable medical supplies. Providers must report sales tax, including amounts reimbursed by Medi-Cal, to the Board of Equalization. For more information, see the *Taxable and Non-Taxable Items* section in the appropriate Part 2 manual.

## **Claim Information**

The following claim information is for disposable medical supplies on the *List of Medical Supplies: Billing Codes, Units and Quantity Limits* and contracted supply spreadsheets.

#### Refills

Medical supply items supplied as refills to the original order are reimbursable only if the supply and quantity billed remains reasonable and necessary, and the existing supply is nearly exhausted. Providers must confirm if any changes/modifications to the order are necessary and not automatically ship on a pre-determined basis.

#### **HCPCS Level II Codes**

A complete list of medical supply HCPCS Level II billing codes required on claims are in the *List of Medical Supplies: Billing Codes, Units and Quantity Limits* spreadsheet. For Medi-Cal reimbursement, the medical supply HCPCS billing code on the claim must be appropriate for the product dispensed.

#### **Universal Product Number (UPN)**

The UPN, a unique product identifier, is required on claims for selected medical supply items. «Claims for contracted medical supplies require the UPN, as provided on the appropriate list of contracted supplies. Refer to the *List of Medical Supplies: Billing Codes, Units and Quantity Limits* spreadsheet.»

The UPN on the claim billed must be the exact UPN for the product dispensed.

#### **UPN Qualifier**

The UPN qualifier is a two-character code that distinguishes the type of UPN. This code is required on every claim line of the *CMS-1500* claim form that contains a UPN. Claims for contracted medical supplies require the UPN qualifiers as provided in the appropriate list of contracted supplies.

For a list of UPN qualifiers and instructions about entering the qualifier/UPN number on the claim, refer to the CMS 1500 Completion section in this manual.

## Claim and Invoice Attachment Examples

Providers may refer to both claim and invoice examples in the *Medical Supplies: Billing Examples* section.

### "By Report"

Certain medical supply claims require documentation of product cost (an invoice, manufacturer's catalog page or price list), as an attachment to the claim, for reimbursement. The product name must be clearly identifiable on the documentation. "By Report" items are in the *List of Medical Supplies: Billing Codes, Units and Quantity Limits* spreadsheet.

### **Invoice Requirements for Medical Supplies**

Invoice attachments submitted with claims for medical supplies without all of the required data elements will be denied. Invoices containing insufficient pricing documentation also will be denied. (See "Invoice Requirements" in the *Medical Supplies: Billing Examples* section in this manual.)

### **Invoice Certification for Medical Supplies**

Certain charges appearing on invoices may not be billable to the Medi-Cal program. Providers are required to include the certification statement below <u>written exactly as shown</u> for each invoice attachment. The item claimed must be clearly identified on the invoice if the item number is not identified on the statement.

"I certify that I have properly disclosed and appropriately reflected a discount or other reduction in price obtained from a manufacturer or wholesaler in the costs claimed or charges on this invoice identified by item number \_\_\_\_\_\_ as stated in 42 U.S.C. 1320a-7b (b) (3) (A) of the Social Security Act and this charge does not exceed the upper billing limit as established in the *California Code of Regulations* (CCR), Title 22, Section 51008.1 (a) (2) (D)."

**Note:** The certification statement may be typed, printed or stamped onto the invoice, or otherwise attached to the claim.

#### «Intravenous or Intra-arterial Solutions: Administration Sets

This section includes instructions for submitting claims for "single product" and "separate component" intravenous solutions administration sets with HCPCS code A4223.>>

#### <u>«Single Product: Administration Sets</u>

A single product that is considered to be a "complete administration set" (in other words, a unit that by itself can be used to deliver I.V. fluids to a patient) may be billed with HCPCS code A4223 on a single claim line on the CMS-1500 claim. Code A4223 is entered in the Procedures, Services or Supplies field (Box 24D). The appropriate pricing attachment (invoice, manufacturer catalog page or price list) for the product must be included and the product description from the pricing attachment entered in the Additional Claim Information field (Box 19). The product description on the claim must match the product description on the pricing attachment.

#### Separate Components: Administration Sets

When a complete administration set is made up of separate components that by themselves cannot deliver I.V. fluids to a patient (for example, extension sets, filters, etc.), the components may be grouped together on an I.V. administration set worksheet. HCPCS code A4223 is entered in the Procedures, Services or Supplies field (Box 24D) of the CMS-1500 claim. The total dollar amount from the worksheet is transferred to the Charges field (Box 24F). The worksheet is then submitted with the claim form and product-specific pricing attachment(s). The product description(s) on the I.V. administration set worksheet must match the product description(s) on the pricing attachment(s). The quantity billed should match the total number of separate components from the worksheet and/or pricing attachment.

#### **Individual Components**

The following individual components are also billed using HCPCS code A4223:

- Connecting Device
- Heparin Lock Caps

The appropriate pricing attachment (invoice, manufacturer catalog page or price list) for the product must be included. The product description on the claim must match the product description on the pricing attachment.

# **Legend**

Symbols used in the document above are explained in the following table.

Symbol	Description
<b>((</b>	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
>>	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.