PHYSICIAN ADMINISTERED DRUGS, VACCINES, AND IMMUNIZATIONS

ELIGIBLE PROVIDERS

In order to receive payment, all eligible servicing and billing provider’s National Provider Identifiers (NPI) must be enrolled with South Dakota Medicaid. Servicing providers acting as a locum tenen provider must enroll in South Dakota Medicaid and be listed on the claim form. Please refer to the provider enrollment chart for additional details on enrollment eligibility and supporting documentation requirement.

South Dakota Medicaid has a streamlined enrollment process for ordering, referring, and attending physicians that may require no action on the part of the provider as submission of claims constitutes agreement to the South Dakota Medicaid Provider Agreement.

The following providers may bill for physician administered drugs and vaccines/immunizations (hereafter referred to as “vaccines”) as permitted by their licensure:

- Clinical nurse specialists
- Health department clinics
- Indian Health Service (IHS)
- Nurse midwives
- Nurse practitioners
- Outpatient and inpatient hospital departments
- Pharmacies
- Physician assistants
- Physicians
- Tribal 638 providers

South Dakota Medicaid does not enroll individual pharmacists.

ELIGIBLE RECIPIENTS

Providers are responsible for checking a recipient’s Medicaid ID card and verifying eligibility before providing services. Eligibility can be verified using South Dakota Medicaid’s online portal.

The following recipients are eligible for medically necessary services covered in accordance with the limitation described in this chapter:

<table>
<thead>
<tr>
<th>Coverage Type</th>
<th>Coverage Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicaid/CHIP Full Coverage</td>
<td>Medically necessary services covered in accordance with the limitations described in this chapter.</td>
</tr>
</tbody>
</table>
Medicaid – Pregnancy Related Postpartum Care Only (47) | Coverage restricted to pregnancy related postpartum care only.
---|---
Qualified Medicare Beneficiary – Coverage Limited (73) | Coverage restricted to co-payments and deductibles on Medicare A and B covered services.
Medicaid – Pregnancy Related Coverage Only (77) | Coverage restricted to pregnancy related services only including medical issues that can harm the life of the mother or baby.
Unborn Children Prenatal Care Program (79) | Coverage restricted to pregnancy related services only including medical issues that can harm the life of the mother or baby.

Refer to the Recipient Eligibility manual for additional information regarding eligibility including information regarding limited coverage aid categories.

**COVERED SERVICES AND LIMITS**

**General Coverage Principles**
Providers should refer to the General Coverage Principles manual for basic coverage requirements all services must meet. These coverage requirements include:
- The provider must be properly enrolled;
- Services must be medically necessary;
- The recipient must be eligible; and
- If applicable, the service must be prior authorized.

The manual also includes non-discrimination requirements providers must abide by.

**Physician Administered Drugs**
South Dakota Medicaid covers most drugs and biologics administered in a physician or other licensed practitioner’s office that cannot be self-administered. Physician and other licensed practitioners are responsible for ensuring that the treatment is appropriate based on FDA-approved indications, peer-review journals, and standards of practice. To be covered drugs and biologicals must represent an expense to the physician, other licensed practitioner, or legal entity billing Medicaid. Injections by a physician or other licensed practitioner of medications that can be self-administered are not covered unless justified by the recipient’s condition.

**Administration**
For physician administered drugs, in addition to the HCPCS drug code, providers may separately bill the applicable administration procedure CPT code 96372 or 96373. The code may be billed once for each injection administered on a date of service.

**Units**
Providers must ensure that the units of drugs or biologicals administered to patients are accurately reported in terms of the dosage/units specified in the complete HCPCS code descriptor. Prior to submitting claims providers should review the HCPCS code long descriptor. Provider should not bill
units based on the way the drug is packaged, priced, stored or stocked. The following are examples of how to bill units:

- HCPCS drug descriptor is 10 mg. 700 mgs of the drug is administered to the recipient. The units billed is 70.
- HCPCS drug descriptor is 5 mcg. 5 mgs of drug is administered to the recipient. The units billed is 1.
- HCPCS drug descriptor is 25 mg. 250 mgs of the drug is administered to the recipient. The units billed is 10.

**Pharmacy Acquired Drugs**

Drugs that are administered to a patient as part of a clinic or other outpatient visit are not covered under the pharmacy benefit. Do not bill drugs administered during an outpatient visit through the pharmacy POS system. South Dakota Medicaid does not allow “brown-bagging” or “white-bagging” of prescription drugs administered in an office setting. Pharmacies should not dispense drugs directly to a patient if the drugs are intended for use during a clinic or other outpatient visit.

**Discarded Portion of Administered Drugs**

When a provider must discard the remainder of a single use vial or other single use package after administering a dose or quantity of the drug or biological, provider must bill the amount of the unused and discarded drug on a separate claim line using the JW modifier. Providers are expected to use the package size that minimizes the amount of waste billed to South Dakota Medicaid. For example, if a patient needs 50 mg of drug and the product comes in 50 mg and 100 mg vials, providers should use the 50 mg vial. The line with the JW modifier pays at zero. The recipient may not be billed for discarded drugs.

**Donated Drugs**

South Dakota Medicaid does not reimburse providers for drugs donated to a recipient. The administration of the drugs by a provider is covered. Do not include the code for the drug on the claim for administration.

**340B Drugs**

South Dakota Medicaid does not cover drugs acquired through the 340B program. Providers must “carve out” and not bill South Dakota Medicaid for any drugs acquired through this program. For more information refer to the 340B Drugs manual.

**National Drug Code (NDC)**

Physician administered drugs must be billed with both a HCPCS code and an 11-character NDC with no hyphens or spaces. The Federal Deficit Reduction Act of 2005 (DRA) requires Medicaid state agencies to collect rebates from participating drug manufacturers for physician-administered or dispensed drugs. An NDC is required as it allows the state to identify which manufacturer should be billed for rebates. The NDC is found on the drug container such as a vial, bottle, or tube. The NDC submitted on the claim must be the actual NDC number on the package or container from which the medication was administered. Refer to the CMS 1500 Claim Instructions for information regarding reporting the NDC on a claim.
Prior Authorization
The following physician administered drugs require a prior authorization:

- Aduhelm (Only covered for full coverage Medicaid. Per CMS guidance Aduhelm is not covered for dual-eligible individuals’ by Medicaid as it is considered a Part D drug).
- CAR T Cell Therapy
- Makena
- Spinraza
- Zolgensma
- Synagis
- Tepezza

Please refer to the Prior Authorization website for prior authorization forms.

Bezlotoxumab (Zinplava)
Bezlotoxumab (Zinplava) does not require prior authorization; the following criteria must be met and documented in the recipients’ medical record for coverage of Zinplava:

1. The recipient is 18 years of age or older.
2. The recipient has a confirmed diagnosis of Clostridium difficile infection (CDI) as evidenced by both of the following:
   a. Passage of 3 or more loose bowel movements in 24 or fewer hours; and
   b. A positive stool test for toxigenic Clostridium difficile.
3. The recipient is starting or is currently receiving appropriate antibiotic treatment for CDI for at least 10 days; and
4. Zinplava will be administered during antibacterial drug treatment for recipient’s CDI; and
5. The recipient is at high-risk for CDI recurrence as evidenced by 2 or more of the following risk factors:
   a. Recipient is 65 years of age or older; or
   b. Recipient has had one or more previous CDIs requiring treatment in the past 6 months; or
   c. Recipient is immunocompromised.

Botulinum Toxin (Botox)
Botox requires prior authorization by South Dakota Medicaid and is not covered if treatment is determined to investigational, experimental or cosmetic. Botulinum toxin administration may only be billed every 12 weeks, regardless of the diagnosis. To be medically necessary, the service must meet the following conditions:

- Axillary Hyperhydrosis under the following conditions:
  o For initial therapy, medical records documenting all the following:
    ▪ Potential causes of secondary hyperhidrosis have been ruled out (e.g., hyperthyroidism);
    ▪ The condition is associated with significant functional impairment that is documented in the medical record (e.g., member is unable to perform age-appropriate activities of daily living);
The condition is causing persistent or chronic cutaneous conditions (e.g., skin maceration, dermatitis, fungal infections, secondary microbial infections);

- Condition is refractory to at least 2 months of continuous treatment with a topical agent (e.g., ≥20% aluminum chloride) unless use results in severe dermatitis; and
- Condition is refractory to at least 2 months of continuous treatment with conventional systemic pharmacotherapy (e.g., anticholinergics, beta blockers, or benzodiazepines) unless clinically contraindicated.

For continuation of therapy, medical records documenting both of the following:
- Documentation of positive clinical response to botulinum toxin therapy; and
- Statement of expected frequency and duration of proposed botulinum toxin treatment.

Chronic migraine headaches under the following conditions:
- Recipient has been evaluated by a neurologist or headache specialist; and
- For prevention of chronic migraine headaches: (more than 14 days per month with headaches lasting 4 hours a day or longer), in adults who have tried, (if not medically contraindicated), and failed trials of at least three medications selected from at least two classes of migraine headache prophylaxis medications listed below of at least 2 months (60 days) duration for each medication:
  - Angiotensin-converting enzyme inhibitors/angiotensin II receptor blockers (e.g., losartan, valsartan, lisinopril);
  - Anti-depressants (e.g., amitriptyline, clomipramine, doxepin, mirtazapine, nortriptyline, protriptyline);
  - Anti-epileptic drugs (e.g., divalproex, gabapentin, topiramate, valproic acid);
  - Beta blockers (e.g., atenolol, metoprolol, nadolol, propranolol, timolol);
  - Calcium channel blockers (e.g., diltiazem, nifedipine, nimodipine, verapamil).

Continuing treatment with botulinum toxin injection for ongoing prevention of chronic migraine headaches is considered medically necessary when documentation is submitted showing that:
- Migraine headache frequency was reduced by at least 7 days per month (when compared to pre-treatment average) by the end of the initial trial of 24 weeks; or
- Migraine headache duration was reduced by at least 100 total hours per month (when compared to the pre-treatment average) by the end of the initial trial.

All other uses for Botox must be medically necessary and meet medical necessity criteria:
- It is consistent with the recipient’s symptoms, diagnosis, condition, or injury;
- It is recognized as the prevailing standard and is consistent with generally accepted professional medical standards of the provider’s peer group;
- It is provided in response to a life-threatening condition; to treat pain, injury, illness, or infection; to treat a condition that could result in physical or mental disability; or to achieve a level of physical or mental function consistent with prevailing community standards for diagnosis or condition;
- It is not furnished primarily for the convenience of the recipient or the provider; and
- There is no other equally effective course of treatment available or suitable for the recipient requesting the service which is more conservative or substantially less costly.
Hydroxyprogesterone Caproate (Makena)
Makena requires prior authorization by South Dakota Medicaid. Makena is FDA approved to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. Makena is not intended for use in women with multiple gestations or other risk factors for preterm birth. If prior authorized, approval will be granted for treatment beginning between weeks 16 and 20 of gestation and continuing until week 37 of gestation or delivery, whichever occurs first.

Spinraza (Nusinersen)
Spinraza is covered for the treatment of Spinal Muscular Atrophy (SMA) when prior authorized for patients who meet all the following criteria:

Initial Therapy:
- Diagnosis of spinal muscular atrophy type I, II, or III by, or in consultation with, a neurologist with expertise in the diagnosis of SMA; and
- Submission of medical records (e.g., chart notes, laboratory values) confirming both of the following:
  - The mutation or deletion of genes in chromosome 5q resulting in one of the following:
    - Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13)1,5; or
    - Compound heterozygous mutation (e.g., deletion of SMN1 exon 7[allele 1] and mutation of SMN1 [allele 2]); and
  - Patient has 3 copies or less of SMN2; and
- Patient is not dependent on either of the following:
  - Invasive ventilation or tracheostomy
  - Use of non-invasive ventilation beyond use for naps and nighttime sleep; and
- Submission of medical records (e.g., chart notes, laboratory values) including the baseline Hammersmith Functional Motor Scale Expanded (HFMSE) exam by a board certified neurologist. If the HFMSE is not appropriate for the patient, provide the test used to establish baseline motor ability; and
- Spinraza is prescribed by, or in consultation with, a neurologist with expertise in the treatment of SMA; and
- One of the following:
  - Patient has not previously received gene replacement therapy for the treatment of SMA; or
  - One of the following:
    - Both of the following:
      - Patient recently received gene replacement therapy within the previous 6 months; and
      - Patient has experienced a decline in clinical status since receipt of gene replacement therapy; or
    - Both of the following:
      - Patient has previously received gene replacement therapy; and
• Patient has experienced a declination in clinical status that represents a potential abatement of gene therapy efficacy; and
• Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures; and
• Spinraza dosing for SMA is within accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 12mg for each loading dose; and
• Initial authorization will be for no more than 4 loading doses.

Continuation Therapy:
• Diagnosis of spinal muscular atrophy type I, II, or III by, or in consultation with, a neurologist with expertise in the diagnosis of SMA; and
• Submission of medical records (e.g., chart notes, laboratory values) confirming both of the following:
  o The mutation or deletion of genes in chromosome 5q resulting in one of the following:
    ▪ Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13)1,2; or
    ▪ Compound heterozygous mutation (e.g., deletion of SMN1 exon 7[allele 1] and mutation of SMN1 [allele 2]); and
  o Patient has 3 copies or less of SMN2: and
• Patient is not dependent on either of the following:
  o Invasive ventilation or tracheostomy
  o Use of non-invasive ventilation beyond use for naps and nighttime sleep; and
• One of the following:
  o Patient has not previously received gene replacement therapy for the treatment of SMA; or
  o Both of the following:
    ▪ Patient has previously received gene replacement therapy; and
    ▪ Patient has experienced a declination in clinical status that represented a potential failure or abatement of gene therapy efficacy; and
• Submission of medical records (e.g., chart notes, laboratory values) with the most recent results (< 1 month prior to request) documenting a positive clinical response from pretreatment baseline status to Spinraza therapy as demonstrated by the initial test used to establish baseline motor ability unless that test is no longer appropriate for the patient; and
  o One of the following:
    ▪ Improvement or maintenance of previous improvement of at least a 3 point increase in score from pretreatment baseline; or
    ▪ Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so; or
  o Both of the following:
    ▪ Patient was prescribed Spinraza due to clinical declination after receipt of gene therapy; and
    ▪ Patients clinical status has stabilized after receipt of Spinraza therapy; and
• Spinraza is prescribed by, or in consultation with, a neurologist with expertise in the treatment of SMA; and
• Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures; and
• Spinraza dosing for SMA is within accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 12mg every 4 months, starting 4 months after the last loading dose; and
• Reauthorization will be for no more than 3 maintenance doses (12 months).

Spinraza is not covered for:
• Spinal muscular atrophy without chromosome 5q mutations or deletions.
• Routine concomitant treatment of SMA in patients who have previously received gene replacement therapy.
• Type 0 or IV SMA.

Zolgensma
Zolgensma is covered with a prior authorization for patients who meet all the following criteria:

1. Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation or deletion of genes in chromosome 5q resulting in one of the following:
   a. Homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13); or
   b. Compound heterozygous mutation of SMN1 gene (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2]); and

2. One of the following:
   a. Diagnosis of SMA by a board-certified pediatric neurologist with expertise in the diagnosis of SMA; or
   b. Both of the following:
      • Diagnosis of SMA based on the results of SMA newborn screening; and
      • Submission of medical records (e.g., chart notes, laboratory values) confirming that patient has 3 copies or less of SMN2 gene: and

3. For use in a neonatal patient born prematurely, the full-term gestational age has been reached; and

4. One of the following:
   a. Both of the following:
      (1) Patient is less than or equal to 6 months of age
      (2) Patient does not have advanced SMA at baseline (e.g., complete paralysis of limbs); or
   b. All the following:
      (1) Patient is greater than 6 months of age, but less than 2 years of age; and
      (2) One of the following:
         A. Both of the following:
i. Patient has previously received SMN modifying therapy [e.g. Spinraza (nusinersen)] for the treatment of SMA before 6 months of age with positive clinical response; and

ii. Submission of medical records (e.g., chart notes, laboratory values) confirming patient does not have advanced SMA as defined by the fact that the patient has not shown evidence of clinical decline while receiving SMN modifying therapy [e.g. Spinraza (nusinersen)]; or

B. Both of the following:

i. Patient has previously received SMN modifying therapy [e.g. Spinraza (nusinersen)] for the treatment of later-onset SMA before 2 years of age with positive clinical response; and

ii. Submission of medical records (e.g., chart notes, laboratory values) confirming patient does not have advanced SMA as defined by the fact that the patient has not shown evidence of clinical decline while receiving SMN modifying therapy [e.g. Spinraza (nusinersen)]; or

C. Patient has recently been diagnosed with symptomatic later-onset SMA within the previous 6 months; and

5. Patient is not dependent on either of the following:
   a. Invasive ventilation or tracheostomy
   b. Use of non-invasive ventilation beyond use for naps and nighttime sleep; and

6. Zolgensma is prescribed by a board-certified pediatric neurologist with expertise in the treatment of SMA; and

7. Patient is not to receive routine concomitant SMN modifying therapy [e.g., Spinraza (nusinersen)] (patient’s medical record will be reviewed and any current authorizations for SMN modifying therapy will be terminated upon Zolgensma approval; patient access to subsequent SMN modifying therapy will be assessed according to respective coverage policy of concomitant agent); and

8. Patient does not have an elevated anti-AAV9 antibody titer above 1:50; and

9. Patient has LFTs less than 2X ULN determined by a certified lab; and

10. Patient has received no treatment with immunosuppressive therapy in the 3 months prior to starting Zolgensma treatment (e.g., corticosteroids, cyclosporine, tacrolimus, methotrexate, cyclophosphamide, intravenous immunoglobulin, rituximab); and

11. Patient does not have symptoms of active viral infection; and

12. Physician attests that the patient, while under the care of the physician, will be assessed on the Hammersmith Functional Motor Scale Expanded (HFMSE) assessment (or the initial test used to establish baseline motor ability unless that test is no longer appropriate for the patient) during subsequent office visits while the patient is 2 to 3 years of age or older following exam scales during subsequent office visits; and

13. Physician acknowledges that South Dakota Medicaid may request documentation, not more frequently than biannually, and not for a period to exceed 3 years, of follow-up patient assessment(s) including, but not necessarily limited to, HFMSE assessments or other applicable assessments while the patient is under the care of the physician; and
14. Patient will receive prophylactic prednisolone (or glucocorticoid equivalent) prior to and following receipt of Zolgensma in accordance with the United States Food and Drug Administration (FDA) approved Zolgensma labeling; and
15. Patient will receive Zolgensma intravenously in accordance with the FDA approved labeling, 1.1 x 1014 vector genomes (vg) per kg of body weight; and
16. Patient has never received Zolgensma treatment in their lifetime; and
17. Authorization will be for no longer than 14 days from approval or until 2 years of age, whichever is first.

Zolgensma is not covered for:
- The treatment of pre-symptomatic patients diagnosed by newborn screening who have more than 3 copies of the SMN2 gene.
- The treatment of symptomatic later-onset SMA older than 2 years of age.
- SMA without chromosome 5q mutations or deletions.
- The routine combination treatment of SMA with concomitant SMN modifying therapy.

**Synagis/Respigam**

Synagis and Respigam are covered by South Dakota Medicaid if prior authorized. It is only covered from November 1st of each calendar year through March 31st of the following calendar year. It may be covered outside of this time period if determined medically necessary by the South Dakota Medicaid Medical Director. A child must meet all of the following criteria:
- The medication has been recommended by a neonatologist, pediatric pulmonologist, or pediatric cardiologist; and
- The child meets one of the following categories listed below:
  - Children under 1 year of age at the onset of RSV season who were 28 & 0/7 weeks or less gestational age at birth; or
  - Children under 6 months of age at the onset of the RSV season who were born between 28 & 1/7 and 32 & 0/7-weeks gestational age at birth; or
  - Children under 3 months of age at the onset of the RSV season or who are born during the RSV season (11/1-3/31) who were between 32 & 1/7 and 35 & 0/7 weeks gestational age at birth with one of these 2 risk factors: day care attendance or a sibling in the household less than 5 years of age; or
  - Children under 2 years of age at the onset of the RSV season with evidence of ongoing lung disease such as bronchopulmonary dysplasia or cystic fibrosis requiring treatment with oral bronchodilators, supplemental oxygen, diuretics, or nebulized or inhaled medications to stabilize the disease in the last 6 months; or
  - Children under 2 years of age at the onset of the RSV season with evidence of hemodynamically significant cyanotic or acyanotic congenital heart disease and 1 of the following: receiving medication to control congestive heart failure, moderate to severe pulmonary hypertension, or undergoing surgical procedures that use cardiopulmonary bypass; or
Children under 2 years of age at the onset of the RSV season with immunodeficiencies that may make them more susceptible to severe lower respiratory tract disease related to RSV; or

Any child under 2 years of age at the onset of the RSV season felt to be at high risk for significant lower respiratory tract illness related to RSV.

Providers must submit the request using the Synagis Prior Authorization Request Form.

Tepezza

Tepezza (CPT J3241) is covered when the following criteria is met, and it is prior authorized by South Dakota Medicaid:

- Recipient must be 18 years of age or older; and
- Tepezza is prescribed by, or in consultation with, an endocrinologist or ophthalmologist with expertise in the treatment of Graves’ disease associated with thyroid eye disease (TED); and
- The recipient has had an inadequate response with, or has a contraindication or intolerance to, corticosteroids used for the treatment of TED (e.g., prednisone, methylprednisolone, dexamethasone); and
- Recipient has a diagnosis of moderate to severe Thyroid associated orbitopathy (thyroid eye disease):
  - Associated with at least one of the following:
    - Lid retraction ≥ 2 mm; or
    - Moderate or severe soft tissue involvement; or
    - Exophthalmos ≥ 3 mm above normal for race and gender; or
    - Diplopia; and
  - One of the following:
    - Patient must be euthyroid with thyroid function under control; or
    - Mild hypothyroidism or hyperthyroidism undergoing treatment to correct and/or maintain euthyroid; and
- Onset of TED symptoms within 9-12 months prior to starting Tepezza treatment; and
- TED clinical activity score of greater than or equal to four (4); and

### Clinical Activity Score for Graves Orbitopathy

<table>
<thead>
<tr>
<th>Item</th>
<th>Score</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Pain</td>
<td>1</td>
<td>Painful oppressive feeling on or behind the globe, during the last four (4) weeks</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Pain on attempted up, side or down gaze, during the last four (4) weeks</td>
</tr>
<tr>
<td>Redness</td>
<td>3</td>
<td>Redness of eyelid(s)</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Diffuse redness of the conjunctiva, covering at least one (1) quadrant</td>
</tr>
<tr>
<td>Swelling</td>
<td>5</td>
<td>Swelling of eyelid(s)</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Chemosis</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>Swollen caruncle</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Increase of proptosis of greater than or equal to 2mm during a period of 1-3 months</td>
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</tbody>
</table>
Physician Administered Drugs, Vaccines, and Immunizations

<table>
<thead>
<tr>
<th>Impaired function</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>9</td>
<td>Decrease of eye movements in any direction greater than or equal to 50 during a period of 1-3 months</td>
</tr>
<tr>
<td>10</td>
<td>Decrease of visual activity of greater than or equal to one (1) line(s) on the Snellen chart (using a pinhole) during a period of 1-3 months</td>
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</tbody>
</table>

- Recipient does not require immediate surgical ophthalmological intervention; and
- Recipient does not have clinically significant optic neuropathy (Individual has not had a decrease in best corrected visual acuity (BVCA) within the previous six months, i.e., decrease in vision of 2 lines on the Snellen chart, new visual field defect, or color defect secondary to optic nerve involvement; and
- Recipient does not have corneal decompensation unresponsive to medical management; and
- Recipient is euthyroid, mild hypothyroid, mild hyperthyroid (defined as free thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below the normal limits) or seeking care for dysthyroid state from an endocrinologist or other provider experienced in the treatment of thyroid diseases; and
- If the recipient is a diabetic, the recipient is being managed by an endocrinologist or other provider experienced in the treatment and stabilization of diabetes; and
- Individual is not pregnant.

**Vaccine Coverage**
South Dakota Medicaid covers medically necessary vaccines and follows the Center for Disease Control immunization schedule, which is available on the CDC website: [https://www.cdc.gov/vaccines/schedules/index.html](https://www.cdc.gov/vaccines/schedules/index.html).

Vaccines may be administered by physicians, other licensed practitioners, or nurses as allowed within their scope of licensure. Vaccines may be administered by a pharmacy when ordered by a physician, other licensed practitioners or under a collaborative agreement per SDCL 36-11-19.1. Flu vaccines do not require an order by a physician or other licensed practitioner if pharmacist meets the criteria in ARSD Ch. 20:51:28. Based on the Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against Covid-19 South Dakota Medicaid will reimburse pharmacist administered claims for recipients age 3 years old or older without a physician or other licensed practitioner’s order. This temporary coverage exception will end when the COVID-19 Emergency Declaration ends. A Primary Care Provider/Health Home Provider referral is not required for vaccines.

**Vaccine for Children Program**
Providers must obtain vaccines for recipients 18 years of age and under from the Vaccines for Children Program if the vaccine is available through the program. A list of available vaccines is provided here. South Dakota Medicaid reimburses the administration fee for vaccines available through this program; vaccines are paid at $0. Providers must bill state supplied vaccines with the SL modifier, indicating the vaccine was supplied through the Vaccine for Children’s program. Claims for vaccines that are available through the Vaccines for Children program for recipients 18 years of age and under that do not include the SL modifier will pay at $0.
If state supplied vaccines is temporarily unavailable from the VFC program, you must submit the claim on paper with supporting documentation such as a letter from the Department of Health stating they are out of the vaccine.

**Pediatric Vaccination Counseling**

South Dakota Medicaid covers vaccination counseling by providers authorized to administer COVID-19 and childhood vaccines, including those authorized under the HHS COVID-19 PREP Act declaration, for children under age 21. Pediatric vaccination counseling consists of discussing CDC vaccine recommendations, benefits, possible side effects, and answering any questions the recipient or their parents have regarding the vaccine(s). Providing a handout or written information does not constitute counseling. Counseling may be provided to a parent or guardian if age appropriate and for the direct benefit of the child. Vaccine counseling and the types of vaccine counseled on must be documented in the medical record. Vaccine counseling is considered included in a well-child visit and is not separately billable in addition to a well-child visit. Counseling is not separately reimbursed if it is or can be included in a vaccine administration code. Pediatric vaccination counseling can be billed using the following codes:

- **99402** - Pediatric vaccine counseling. One unit of 99402 is inclusive of all counseling provided that day, including if counseling was for multiple types of non-COVID-19 vaccines.
- **99403** - COVID-19 pediatric vaccine counseling. May be billed in addition to 99402. Coverage is temporary and in effect through one year after the end of the COVID-19 public health emergency.

A total of six counseling sessions (three for each code) per recipient, per calendar, year are reimbursable. Counseling may be provided via telemedicine. Counseling may also be provided via audio only if the visit was initiated by the recipient and the recipient does not have access to face-to-face audio/visual telemedicine technology. Telemedicine and audio only services must be billed in accordance with the [Telemedicine Services](#) billing manual.

**FQHC/RHCs**

Refer to the [FQHC/RHCs](#) manual for coverage, reimbursement, and claim instructions.

**IHS/Tribal 638 Facilities**

Refer to the [IHS and Tribal 638 Facilities](#) manual for coverage, reimbursement, and claim instructions.

**Postpartum Coverage**

Vaccinations during postpartum coverage are covered if indicated by the CDC. Please note that postpartum coverage may end before the full series of Hepatitis A and Hepatitis B vaccines are administered and the recipient may not have continued Medicaid coverage.

**NON-COVERED SERVICES**

**General Non-Covered Services**

Providers should refer to [ARSD 67:16:01:08](#) or the [General Coverage Principles](#) manual for a general list of services that are not covered by South Dakota Medicaid.
**Vaccine Non-Covered Services**
A vaccine code is not covered when billed without a vaccine administration code. A vaccine administration code is not covered when billed without a vaccine code. Reimbursement for vaccines is not available as a service provided by school districts under the individualized education program (IEP) or care plan.

**DOCUMENTATION REQUIREMENTS**

**General Requirements**
Providers must keep legible medical and financial records that fully justify and disclose the extent of services provided and billed to South Dakota Medicaid. These records must be retained for at least 6 years after the last date a claim was paid or denied. Please refer to the [Documentation and Record Keeping](#) manual for additional requirements.

**REIMBURSEMENT AND CLAIM INSTRUCTIONS**

**Timely Filing**
South Dakota Medicaid must receive a provider’s completed claim form within 6 months following the month the service was provided. Requests for reconsiderations will only be considered if they are received within the timely filing period or within 3 months of the date a claim was denied. The time limit may be waived or extended by South Dakota Medicaid in certain circumstances. Providers should refer to the [General Claim Guidance](#) manual for additional information.

**Third-Party Liability**
Medicaid recipients may have one or more additional source of coverage for health services. South Dakota Medicaid is generally the payer of last resort, meaning Medicaid only pays for a service if there are no other liable third-party payers. Providers must pursue the availability of third-party payment sources and should use the Medicare Crossover or Third-Party Liability billing instructions when applicable. Providers should refer to the [General Claim Guidance](#) manual for additional information.

**Reimbursement**
The rate of payment for physician administered drugs, vaccines, and administration codes is limited to the lesser of the provider’s usual and customary charge or the amount specified on the department’s [physician non-laboratory services fee schedule](#). If the procedure code is not listed in the fee schedule, the procedure is payable at 40 percent of the provider’s usual and customary charge. Claims for vaccines that are available through the Vaccines for Children program pay at $0.

Physician administered drugs and vaccines provided by a nurse practitioner, clinical nurse specialist, or physician assistant are reimbursed at the same rate as a physician.

**Claim Instructions**
Physician administered drugs, vaccines, and administration are billed on a CMS 1500 Claim Form with the exception of IHS, Outpatient Hospitals, and Inpatient Hospitals which must be billed on a UB-04 claim form. Please refer to our [website](#) for CMS 1500 and UB-04 claim instructions.
The vaccine code should be billed as 1 unit per vaccine; do not bill in milliliters. Flu vaccine claims do not require a physician or other licensed practitioner order. All other vaccines must include the ordering physician or other licensed practitioner’s name and NPI number in block 17 and 17b of the claim form.

UB-04 Claims Documentation
An itemized invoice must be submitted with claims that include billed charges totaling a $100,000 or more for Revenue Codes 250-259, 630-636, and 890-899.

Hospitals are required to report vaccine administration charges under the revenue code 0771.

Pharmacy COVID-19 Vaccine Claim Instructions
Pharmacy claims for COVID-19 vaccine administration must be submitted through the Pharmacy Point of Sale System (POS). Claim submissions for administration of the COVID-19 vaccine must include the NCPDP fields as depicted below.

<table>
<thead>
<tr>
<th>NCPDP Field Name</th>
<th>NCPDP Field Number</th>
<th>First Dose</th>
<th>Second Dose (If Applicable)</th>
<th>Single Dose (When Available)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional Service Code (DUR-PPS)</td>
<td>440-E5</td>
<td>MA = Medication Administration</td>
<td>MA = Medication Administration</td>
<td>MA= Medication Administration</td>
</tr>
<tr>
<td>Day Supply</td>
<td>405-D5</td>
<td>1-Day</td>
<td>1-Day</td>
<td>1-Day</td>
</tr>
<tr>
<td>Submission Clarification Code (SCC)</td>
<td>420-DK</td>
<td>2 = Other Override</td>
<td>6 = Starter Dose</td>
<td>Blank</td>
</tr>
<tr>
<td>Ingredient Cost Submitted</td>
<td>409-D9</td>
<td>$0.00 ($0.01 if system requires)</td>
<td>$0.00</td>
<td>$0.00 ($0.01 if system requires)</td>
</tr>
<tr>
<td>Gross Amount Due</td>
<td>430-DU</td>
<td>U&amp;C</td>
<td>U&amp;C</td>
<td>U&amp;C</td>
</tr>
<tr>
<td>Product / Service ID / NDC</td>
<td>407-D7</td>
<td>EUA approved NDC</td>
<td>EUA Approved NDC</td>
<td>EUA Approved NDC</td>
</tr>
<tr>
<td>Fill Number</td>
<td>403-D3</td>
<td>00</td>
<td>01</td>
<td>00</td>
</tr>
</tbody>
</table>

Pharmacy Flu Vaccine for recipients 19 or older
Flu vaccines billed by a pharmacy for Medicaid recipients 19 years of age or older are billable through the pharmacy point of sale system. The flu vaccine administration will be paid in the form of the pharmacy dispensing fee. A valid prescriber NPI is required in accordance with current South Dakota pharmacy rules.

Claims for vaccines administered by the pharmacy must be submitted with a pharmacy taxonomy code beginning with 3336. Claims submitted without a taxonomy code or with a taxonomy code that does not begin with 3336 will deny.
Pharmacy Other Vaccine Claim Instructions
With the exception of COVID-19 vaccines and flu vaccines for recipients 19 or older pharmacies must submit all other vaccine and vaccine counseling claims on a CMS 1500 claim form using the pharmacy’s NPI number. Pharmacies must bill vaccine administration using CPT codes 90471, 90472, 90473 or 90474. The administration code must be listed first, followed by the appropriate vaccine CPT code. Claims without both CPT codes in the correct order will deny.

Pharmacy flu vaccine claims on a CMS 1500 do not require a prescriber order. All other vaccines must include the prescriber’s name in box 17 and their NPI number in box 17b of the claim form. Please note this requirement is temporarily suspended for recipients age 3 years old or older based on the Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against Covid-19. South Dakota Medicaid will reimburse pharmacist administered claims for recipients age 3 years old or older without a prescriber’s name being required on the claim. This temporary coverage exception will end when the COVID-19 Emergency Declaration ends.

Vaccines for Children Claim Instructions
Providers must bill state supplied vaccines with the SL modifier.

REFERENCES
- Administrative Rule of South Dakota (ARSD)
  - 67:16:11:05.01. Rate of payment – Immunizations
  - 67:16:02:03. Rate of payment – (9)
  - 67:16:02:16. Billing requirements -- Modifier codes -- Provider identification numbers
- South Dakota Medicaid State Plan
- Code of Federal Regulations

QUICK ANSWERS
1. Does a child/adult need a referral from their Primary Care Provider/Health Home Provider for South Dakota Medicaid to cover a vaccine?

   No, a referral is not needed for the administration of a vaccine.

2. Can a pharmacy bill for vaccines through the Point of Sale system?

   COVID-19 vaccines/administration can be billed through the Point of Sale system. Flu vaccines for Medicaid recipients 19 years or older can also be billed by a pharmacy through Point of Sale. Pharmacies must bill all other vaccines on a CMS 1500 claim form.

3. Can a recipient acquire a physician administered drug through a pharmacy and take it to a physician or other licensed practitioner for administration?
No, physician administered drugs must not be billed to South Dakota Medicaid through the point of sale.

4. If a recipient’s primary health insurance requires a physician administered drug to be dispensed by a particular pharmacy, how should the drug be billed to South Dakota Medicaid?

South Dakota Medicaid does not cover physician administered drugs through the point of sale. The drug must be billed to South Dakota Medicaid on a CMS 1500 claim form.

5. What reimbursement is available for vaccines acquired through the Vaccines for Children Program?

South Dakota Medicaid reimburses vaccines available through this program that are administered to recipients under age 19 at $0. The administration fee is reimbursed in accordance with the department’s fee schedule.

6. What vaccines are covered for individuals with limited Medicaid coverage?

All medically necessary vaccines that South Dakota Medicaid covers for full coverage recipients are covered for women in aid categories 77, 79 and 47. Medicaid will pay the co-payments and deductibles for recipients on aid category 73 if the vaccine is a Medicare part B covered service. Vaccines in the postpartum period for women in Aid category 79 are limited to vaccines administered during the inpatient stay.

7. Are vaccines included in an FQHC/RHC encounter payment?

Vaccines/immunizations and administration are factored into each provider's PPS rate and are reimbursed as part of the PPS per diem when furnished incidental to a reimbursable medical PPS encounter. It is recommended that providers screen a recipient's immunization status and administer appropriate vaccines when seeing a recipient for their Well-Child or Well-Adult visit. For purposes of data collection, it is required that immunizations provided during a PPS encounter be included on the claim for PPS reimbursement.

FQHCs/RHCs are allowed to bill for vaccines/immunizations and the associated administration provided on a date of service when a billable medical encounter did not occur. Standalone vaccines/immunizations may not be billed under the FQHCs/RHCs billing NPI. FQHC/RHCs billing for standalone vaccines/immunizations must utilize/acquire a separate billing NPI under a group enrollment with associated servicing NPIs and bill accordingly. The servicing provider must be enrolled with South Dakota Medicaid. Standalone vaccines/immunizations and the associated administration code will be reimbursed on a fee for service basis. Vaccines/immunizations may not be administered on a separate day than an FQHC/RHC
encounter for the purpose of increasing the provider’s reimbursement. For more information please refer to the FQHC/RHC Services manual.