VACCINES:
How to create a successful vaccine program

KEEP CALM AND VACCINATE
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Governor, Florida Chapter

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Nothing to disclose and no conflicts of interest
Overview

- Vaccine Overview
- Vaccine Guidelines
- Purchasing: Supply, Manufacturers, Storage, Returns
- Reimbursement
  - Codes
  - Billing Assistance
  - Commercial
  - Medicare
Edward Jenner credited as Father of Immunology

Observed milkmaids who contracted cowpox (variolae vaccinae) did not develop smallpox (variola major and minor).

Vacca is Latin for from cows, Varius is Latin for spotted

Took pus from a milkmaid, Sarah Nelmes, and inoculated James Phipps

Phipps develops cowpox

Jenner then inoculates Phipps with pus from smallpox scabs

Phipps does not develop disease

Vaccination invented, possibly greatest advancement in medicine
Figures 1 and 2 should be read with the footnotes that contain important general information and considerations for special populations.

**Figure 1. Recommended Immunization schedule for adults aged 19 years or older by age group, United States, 2017**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>19–21 years</th>
<th>22–26 years</th>
<th>27–59 years</th>
<th>60–64 years</th>
<th>≥ 65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza&lt;sup&gt;3&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Td/Tdap&lt;sup&gt;2&lt;/sup&gt;</td>
<td></td>
<td></td>
<td>Substitute Tdap for Td once, then Td booster every 10 yrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMR&lt;sup&gt;2&lt;/sup&gt;</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAR&lt;sup&gt;4&lt;/sup&gt;</td>
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<td></td>
<td>1 or 2 doses depending on indication</td>
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<td></td>
</tr>
<tr>
<td>HZV&lt;sup&gt;3&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td>2 doses</td>
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<tr>
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<td>3 doses</td>
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<tr>
<td>PCV13&lt;sup&gt;7&lt;/sup&gt;</td>
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<td></td>
<td></td>
<td>1 dose</td>
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<tr>
<td>PPSV23&lt;sup&gt;7&lt;/sup&gt;</td>
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<td></td>
<td></td>
<td>1 or 2 doses depending on indication</td>
<td>1 dose</td>
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<tr>
<td>HepA&lt;sup&gt;8&lt;/sup&gt;</td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>HepB&lt;sup&gt;8&lt;/sup&gt;</td>
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<td></td>
<td>3 doses</td>
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<tr>
<td>MenACWY or MPSV&lt;sup&gt;10&lt;/sup&gt;</td>
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<td></td>
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<td>1 or more doses depending on indication</td>
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<td>Hib&lt;sup&gt;11&lt;/sup&gt;</td>
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<td>1 or 3 doses depending on indication</td>
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</table>

*Yellow* Recommended for adults who meet the age requirement, lack documentation of vaccination, or lack evidence of past infection

*Purple* Recommended for adults with additional medical conditions or other indications

*No recommendation*
### Figure 2. Recommended Immunization schedule for adults aged 19 years or older by medical condition and other indications, United States, 2017

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Pregnant (excl. HIV infection)</th>
<th>HIV Infection CD4+ cell count</th>
<th>Complement deficiencies</th>
<th>Renal failure, end-stage renal disease, on hemodialysis</th>
<th>Heart or lung disease, chronic alcoholism</th>
<th>Chronic liver disease</th>
<th>Diabetes</th>
<th>Healthcare personnel</th>
<th>Men who have sex with men</th>
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</thead>
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<tr>
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<td>1 dose annually</td>
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<td></td>
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<td></td>
<td></td>
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<tr>
<td>Td/Tdap²</td>
<td>1 dose each pregnancy</td>
<td></td>
<td></td>
<td>Substitute Tdap for Td once, then Td booster every 10 yrs</td>
<td></td>
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<tr>
<td>MMR³</td>
<td>contraindicated</td>
<td></td>
<td></td>
<td>1 or 2 doses depending on indication</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAR¹</td>
<td>contraindicated</td>
<td></td>
<td></td>
<td>2 doses</td>
<td></td>
<td></td>
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<tr>
<td>HZV⁵</td>
<td>contraindicated</td>
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<td>1 dose</td>
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<tr>
<td>HPV-Female⁶</td>
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<td></td>
<td></td>
<td>3 doses through age 26 yrs</td>
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<tr>
<td>HPV-Male⁴</td>
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<td></td>
<td></td>
<td>3 doses through age 26 yrs</td>
<td>3 doses through age 21 yrs</td>
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<tr>
<td>PCV13⁷</td>
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<td></td>
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<td>1 dose</td>
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<tr>
<td>PPSV23¹</td>
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<td></td>
<td></td>
<td>1, 2, or 3 doses depending on indication</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>HepA⁸</td>
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<td></td>
<td>2 or 3 doses depending on vaccine</td>
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<td></td>
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<tr>
<td>HepB⁹</td>
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<td></td>
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<td>3 doses</td>
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<tr>
<td>MenACWY or MPSV⁴</td>
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<td>1 or more doses depending on indication</td>
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<tr>
<td>MenB¹⁰</td>
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<td>2 or 3 doses depending on vaccine</td>
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<tr>
<td>Hib¹¹</td>
<td></td>
<td></td>
<td></td>
<td>3 doses post-HSCT recipients only</td>
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</tbody>
</table>

- **Yellow**: Recommended for adults who meet the age requirement, lack documentation of vaccination, or lack evidence of past infection.
- **Purple**: Recommended for adults with additional medical conditions or other indications.
- **Red**: Contraindicated
- **White**: No recommendation

¹ Importantly, the use of a vaccine for pregnant women should be balanced with the risks of severe flu disease.
² Some data indicates Hib may be increased for use in adults.
³ Varicella vaccine contraindicated for adults with a history of chicken pox.
⁴ Varicella vaccine recommended for all adults who have not had varicella vaccination or varicella infection.
⁵ Herpes zoster vaccine recommended for adults aged 60 years or older.
⁶ Human papillomavirus vaccine recommended for all men and women aged 26 years or younger who have not previously received all recommended doses.
⁷ Tetanus, diphtheria, and acellular pertussis vaccine (Tdap) recommended every 10 years for adults aged 18 to 64 years who have not previously received Tdap.
⁸ A second dose of human papillomavirus vaccine (HPV2) recommended at 6 to 12 months and at the age of 15 to 26 years.
⁹ MenACWY vaccine recommended for all adults aged 18 through 55 years who have not previously received MenACWY vaccine.
¹⁰ MenB vaccine recommended for all adults aged 19 through 55 years who have not previously received MenB vaccine.
¹¹ Hib vaccine recommended for adults aged 18 through 55 years who have not previously received Hib vaccine.
Pneumonia

- 2 vaccines available, Prevnar-13 and Penumovax-23
- Total of 1 dose of Prevnar-13 and 2 doses of Pneumovax-23
- Initially give Prevnar-13 when indicated, a year later Pneumovax-23 and 5 years later repeat Pneumovax-23
- If already received Pneumovax-23 then give Prevnar-13 and follow up with Pneumovax-23 5 years after Pneumovax-23
- Special category of immunocompromised conditions, asplenia, cochlear implant of CSF leak should receive Prevnar-13 followed by Pneumovax-23 at 8 week interval
Pneumonia Vaccine Indications

- All adults age 65 and up
- All adults 19 and up with specific medical conditions
  - Diabetes
  - Congestive Heart Failure, Cardiomyopathy, Chronic Heart Disease
  - Chronic Lung Disease, Chronic Obstructive Pulmonary Disease, Asthma
  - Chronic Liver Disease, Cirrhosis, Alcoholism
  - Cigarette Smokers
  - Congenital or Functional Asplenia, sickle cell disease, hemoglobinopathies, splenectomy
  - Immunocompromised conditions, HIV, Combined B or T lymphocyte deficiency, acquired immunodeficiency, complement and phagocytic disease, radiation therapy, long term corticosteroids
  - Chronic Renal Failure, Nephrotic Syndrome
  - Leukemia, lymphoma, malignancy, multiple myeloma, organ transplant
  - Cochlear Implant and CSF leak
All adults should receive yearly Flu vaccine

Nasal live vaccine not advised

Egg allergy is only a contraindication if angioedema, respiratory distress or severe illness

Hives from eggs is not a contraindication

Recombinant vaccine available for egg allergy

Trivalent and Quadravalent available

High dose available for over age 65
Tetanus, diphtheria, pertussis (Tdap)

- One dose after age 19
- Resume dT every 10 years
- Pregnant women should receive Tdap in third trimester of each pregnancy
- Vaccination helps to protect newborns before age 6 months who can not be vaccinated
- Create a circle of protection
1 in 3 people develop shingles
Vaccine reduces incidence by 70%
All adults age 60 should receive vaccine
Do not need to check prior varicella status
Live vaccine contraindicated in immunosuppression
- Medication induce e.g. biologics
- Chronic immunosuppression
- Bone marrow and lymphatic system suppression
- HIV with CD 4 + <200
- 1 in 3 people develop shingles
- Vaccine reduces incidence by 90%
- All adults age 50 should receive vaccine
- Do not need to check prior varicella status
- Recombinant Vaccine
- CDC Recommendations
  - Shingrix for all immunocompetent adults aged 50 years and older (14-1 vote)
  - For immunocompetent adults who previously received Zostavax (12-3) vote
  - Shingrix preferred over Zostavax (8-7 vote)
Hepatitis A

- 2 doses at 0 and 6 months or Hep A/B combination at 0, 1, 6 months
- Any adult who wishes Hep A protection
- Chronic liver disease
- Receiving clotting factor concentrates
- Men who have sex with men
- Drug Use
- Research lab setting
- Travel risk
Hepatitis B

- 3 doses at 0, 1, 6 months
- Indicated for adults seeking protection from Hep B
- Men who have sex with men, any adult with multiple sex partners
- Living in house with Hep B infected individuals
- Healthcare workers or anyone exposed to blood
- IV drug uses
- Liver disease including Hep C, cirrhosis, alcoholic liver disease, fatty liver disease, autoimmune hepatitis, AST and ALT twice normal
- End state renal disease, hemodialysis
- HIV
- Diabetes
- Pregnant women exposed to Hep B
- At risk travelers
2 types of vaccines
- Menactra for A,C, W, Y
- Bexsero or Trumenba for Type B

Menactra 1 dose every 5 years while at risk
Bexsero 2 doses, 4 weeks apart every 5 years while at risk
Trumenba 3 doses at 0, 1-2, 6 months every 5 years while at risk

At risk includes
- College students
- Military Recruits
- Microbiologists who work with Neisseria
- Travel exposure

Special categories
- Asplenia and complement deficiencies should receive Menactra 2 doses at 8 week interval and Bexsero 2 doses at 4 week interval each every 5 years
- HIV infected should received Menactra 2 dose series at 8 week interval and then every 5 years

Bexsero and Trumenba are not interchangeable
Human Papillomavirus
Prevention of cervical, anal, penile and throat cancer
3 dose series at 0, 1-2, 6 months
All female ages 9-26
All males age 9-21
Males age 21-26 if male having sex with male
Immunocompromised conditions including B and T lymphocyte deficiency, malignancy, transplantation, autoimmune disease and immunosuppressive therapy
Supply side

- Buy direct from manufacturer
  - Merck, Aventis, Pfizer, Glaxo, etc.
- Group purchasing organization e.g. Atlantic Health Partners, et. al.
- Buy multiple vaccines for discount
- Defer paying invoice for several months
- Pay promptly on due date for further discounts
- Order what is needed to avoid vaccine loss from expiration
- Many manufactures will take back unused vaccines and credit account
Manufacturers and Vaccines

- **Merck**: [www.merckvaccines.com](http://www.merckvaccines.com)
  - Gardasil-9
  - Zostavax
  - Pneumovax-23
  - Hepatitis A (Vaqta)
  - Hepatitis B (Recombivax)

- **Aventis (Sanofi-Pasteur)**: [www.vaccineshoppe.com](http://www.vaccineshoppe.com)
  - Adacel (Tdap)
  - Menactra (Meningitis A, C, Y, W-135)
  - Fluzone, Quadrivalent and High Dose
  - Yellow Fever
  - Typhim

- **Pfizer**: [www.pfizerprime.com](http://www.pfizerprime.com)
  - Prevnar-13
  - Trumemba (Meningitis B 3 dose)

- **Glaxo Smith Kline”**: [www.gskdirect.com](http://www.gskdirect.com)
  - Bexsero (Meningitis B 2 dose)
  - Energix-B (Hepatitis B)
  - Havrix (Hepatitis B)
  - Fluarix and Flulaval (Influenza quadrivalent)
  - Tdap (Boostrix)
  - Shingrix
Storage Best Practices for Refrigerated Vaccines – Fahrenheit (°F)

1. Unpack vaccines immediately
   - Place the vaccines in trays or uncovered containers for proper airflow.
   - Put vaccines that are first to expire in front.
   - Keep vaccines in original boxes with lids closed to prevent exposure to light.
   - Separate and label by vaccine type and VFC/public or private vaccine.

2. Store vaccine at ideal temperature: 40°F
   - Refrigerated Vaccine
     - Too Cold: Take Action!
     - Too Warm: Take Action!
     - Within Range
     - Report out-of-range temperatures immediately!

3. Use vaccine storage best practices
   - **DO**
     - Make sure the refrigerator door is shut!
     - Replace crispier bins with water bottles to help maintain consistent temperature.
     - Label water bottles “Do Not Drink.”
     - Leave 2-3 inches between all vaccine containers and refrigerator walls.
     - Post “Do Not Unplug” signs on refrigerator and near electrical outlet.
   - **DON’T**
     - Don’t use dormitory-style refrigerator.
     - Don’t use top shelf for vaccine storage.
     - Don’t put food or beverages in refrigerator.
     - Don’t put vaccines or diluents in doors or on floor of refrigerator.
     - Don’t drink from or remove water bottles.

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Centers for Disease Control and Prevention

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Visit [www.cdc.gov/vaccine/safeH](http://www.cdc.gov/vaccine/safeH) or contact your state health department for more information.
Vaccine Storage Best Practices for Frozen Vaccines—Fahrenheit (°F)

1. Unpack vaccines immediately
   1. Place the vaccines in trays or uncovered containers for proper air flow.
   2. Put vaccines that are first to expire in front.
   3. Keep vaccines in original boxes with lid closed to prevent light exposure.
   4. Separate and label by vaccine type and VFC/Public or private vaccine.

2. Store vaccine at ideal temperature range: -58°F to 5°F

3. Use vaccine storage best practices

   **DO**
   - Make sure the freezer door is shut!
   - Use ice packs to help maintain consistent temperature
   - Leave 2 to 3 inches between all vaccines and freezer walls
   - Post “Do Not Unplug” signs on freezer and by electrical outlet

   **DON’T**
   - Don’t use dormitory-style refrigerator/freezer
   - Don’t use combo fridge/freezer unit
   - Don’t put food in freezer
   - Don’t store vaccines in doors

Visit [www.cdc.gov/vaccines/Sem/1](http://www.cdc.gov/vaccines/Sem/1) for more information, or your state health department.
Using Standing Orders for Administering Vaccines: What You Should Know

The use of standing orders for vaccination facilitates the delivery of immunization services to patients in clinics, hospitals, and community settings. Standing orders have been shown to increase vaccination coverage rates.

What are standing orders?
Standing orders authorize nurses, pharmacists, and other appropriately trained healthcare personnel, where allowed by state law, to vaccinate patients according to protocol approved by an institution, physician or other authorized practitioner. Standing orders work by enabling assessment and vaccination of the patient without the need for clinician examination or direct order from the attending provider at the time of the interaction. Standing orders can be established for administering one or more specific vaccines to a broad or narrow set of patients in healthcare settings such as clinics, hospitals, pharmacies, and long-term care facilities.

Who recommends standing orders for vaccination?

The Community Preventive Services Task Force (Task Force): The Task Force recommends standing orders for vaccinations based on strong evidence of effectiveness in improving vaccination rates:

1. In adults and children,
2. When used alone or when combined with additional interventions, and
3. Across a range of settings and populations.

Read the task Force Finding and Rationale Statement at www.thecommunityguide.org/vaccines/standingorders.html.

The Centers for Disease Control and Prevention (CDC): CDC’s Advisory Committee on Immunization Practices (ACIP) specifically recommends standing orders for influenza and pneumococcal vaccinations and several other vaccines.

See Use of Standing Orders Programs to Increase Adult Vaccination Rates: Recommendations of the ACIP. MMWR 2000;49 (No. 85) at www.cdc.gov/mmwr/preview/mmwrhtml/e49h02.htm.

What are the elements of a standing order?
A comprehensive standing order should include the following elements:
1. Who is targeted to receive the vaccine?
2. How to determine if a patient meets criteria for a particular vaccine (e.g., indications, contraindications, and precautions)?
3. Procedures for administering the vaccine (e.g., vaccine name, schedule for vaccination, appropriate needle size, vaccine dosage, route of administration).
4. Provision of any federally required information (e.g., Vaccine Information Statement).
5. How to document vaccination in the patient record.
6. A protocol for the management of any medical emergency related to the administration of the vaccine.
7. How to report possible adverse events occurring after vaccination.

Who is authorized to administer vaccines under standing orders?
Each of the 50 states regulates physicians, nurses, pharmacists, and other health-related practitioners. For further information about who can carry out standing orders in your state, contact your state immunization program or the appropriate state board (e.g., state board of medical/nursing/pharmacy practice).

Who is authorized to sign the standing order?
In general, standing orders are approved by an institution, physician, or authorized practitioner. State law or regulatory agency might authorize other healthcare professionals to sign standing orders.

What should be done with the standing orders after they have been signed?
Signed standing orders should be kept with all other signed medical procedures and protocols that are operational in one's clinic setting. A copy should also be readily available for clinic staff who operate under those standing orders.

Do standing orders need to be renewed (e.g., yearly)?
Generally, standing orders will include an implementation date as well as an expiration date. Periodic review of standing orders is important, because vaccine recommendations may change over time.

Where can I find sample standing orders?
The Immunization Action Coalition has developed templates of standing orders for vaccines that are routinely recommended to children and adults. They are updated as needed and reviewed for technical accuracy by immunization experts at CDC. The most current versions can be accessed by going to www.immunize.org/standingorders.

Technical content reviewed by the Centers for Disease Control and Prevention
www.immunize.org/cdc/gp1204.pdf • Item #13014 (5/15)
<table>
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<tr>
<th>Vaccine</th>
<th>CPT code</th>
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<td>Tdap</td>
<td>$30.65</td>
<td>$47.00</td>
</tr>
<tr>
<td>Yellow Fever</td>
<td>$140.66</td>
<td>$148.31</td>
</tr>
<tr>
<td>Typhim</td>
<td>$92.76</td>
<td>$99.21</td>
</tr>
</tbody>
</table>
Reimbursement tips for Commercial and Medicare

- Dx code for all vaccines Z23
- Know the CPT for each vaccines, check with manufacturer
- All vaccines need a specific CPT code for the vaccine and an administration code
- First administration code is 90471 for commercial, subsequent injection on same visit is 90472 x number of units
- Medicare vaccines for flu (G0008), pneumonia-23and prevnar-13 (G0009), and Hepatitis B (G0010), use G code as first dose administration
- If given on the same day as visit then use modifier 25 on EM code with modifier 59 for vaccines and administration code
- All vaccines for commercial submitted through normal claims process
- Medicare part B vaccines (Flu, Pneumonia, Hepatitis B) submitted through normal claims process
- Zostavax, Tdap, Hep A for Medicare submitted through 3rd party vendor
Certain vaccines are considered Drugs and covered under part D
To bill Medicare part D use www.mytransactRX.com
Allows to check coverage of patients, print out proof, and submit claim through portal and then direct deposit to account
Check for Zostavax, Tdap, Hep A
Limited if patient not covered under drug plan or information not up to date
Advisable to use Advanced Beneficiary Notice for vaccines such as Prevnar, Tdap Hep A and Zostavax.
Medicare strict on coverage guidelines and if patient has received vaccine but does not remember then claim will not be paid, ABN protects provider and can allow reimbursement from patient
Zostavax commercial

- Checkcoveragenow.com
- Similar to transactRX
- Can look at benefits and show to patient
- Submit through normal claims process
Billing examples

- Patient comes in only for high dose flu shot, Medicare or Medicare advantage
  - No physician visit
  - Bill 90662 and G0008

- If see physician for visit then bill:
  - E/M code appropriate level such as 99213-25 G0008-59 and 90662-59
  - Do not use 99211 and vaccines unless patient is specifically having a separate service such as blood pressure adjustment etc
Patient comes in for Flu, Hep B and Pneumonia with Medicare
- G0008,90662,G0009,90732,G0010,90746
If commercial then bill:
- 90471,90686(quadrivalent),90472 for 2 units, 90732,90746
Again if with E/M then modifier 25 on E/M and modifier 59 on each administration and each vaccine
More examples

- Flu, pneumonia and hep B with other vaccines
  - Patient with pneumonia and zostavax
  - Medicare G0009,90732,90472,90736
  - Commercial 99471,90472,90732,90736

- Flu, pneumonia and zostavax
  - Medicare G0008,90662,G0009,90732,90472,90736
  - Commercial 90471,90472 2 units,90732,90736,90685
Questions?
A 62 year old male, has never been vaccinated, presents to your office in October with a history of HIV, diabetes, heart disease, and COPD. He actively smokes and is planning to visit his daughter who gave birth to a healthy baby girl, currently 3 months old. He reports allergy to eggs and only develops mild hives. What vaccines would you advise him to receive?

- A. No vaccines because he has no risk factors
- B. Tdap, Prevnar, Hep A, Hep B, Zostavax, Menactra, and annual Influenza
- C. Prevnar only
- D. Influenza only
- E. Bexsero only
Correct Answer: B

The patient has multiple indications and risk factors for multiple vaccines, which can be given at the same visit. Given the patient’s age, he should receive the zostavax. The patient has HIV which is an indication for Menactra, Hepatitis A and B, and pneumonia. Bexsero has not been indicated for HIV infection as only serotype A,C, W, Y have been seen as increased risk in HIV population, not type B. The patient also has heart and lung disease, which also suggests the need for pneumonia vaccine and the first dose should be Prevnar-13 with Pneumovax-23 the following year and 5 years after. The patient has Diabetes which is an indication for Hepatitis B, and Pneumonia vaccine. Tdap is indicated for all adults, especially if potential exposure to a newborn. Annual flu shot is indicated for all patients and hives from eggs is not a contraindication to the vaccine.

Citation: CDC vaccine schedule