INFORMATION PAPER

DHA-IHD
7 April 2022

SUBJECT: Pneumococcal Disease and Pneumococcal Vaccines

1. Purpose. To describe pneumococcal disease and the vaccines that help prevent it.

2. Facts.

    a. Microbiology. Pneumococcal disease is an infection caused by the bacteria *Streptococcus pneumoniae*, also known as pneumococcus or pneumococci. The bacteria are lancet-shaped, gram-positive, facultative anaerobic organisms. Some pneumococci are encapsulated and are pathogenic (disease causing) for humans. As of 2020, 100 serotypes have been identified: most have been shown to cause serious disease, but only a few produce the majority of infections.

    b. Disease. The most common presentation of a pneumococcal infection among adults is pneumonia. Symptoms generally include fever, chills, rigors, pleuritic chest pain, productive cough, shortness of breath, and rapid breathing. Pneumococcal infections may also lead to bacteremia (infection of the blood) and meningitis (infection causing swelling of the membranes around the brain and spinal cord). In children 2 years of age and younger, bacteremia without a known site of infection is the most common invasive clinical presentation of pneumococcal infection. Pneumococcus is also a common cause of otitis media (middle ear infections), and is the leading cause of meningitis in children under 5 years of age.

    c. Epidemiology. Pneumococci are common inhabitants of the respiratory tract and may be isolated from the nasopharynx of 5% - 90% of healthy individuals. Rates of asymptomatic carriage vary with age, environment, and the presence of upper respiratory infections. Among school-aged children, 20% - 60% may be colonized. Only 5% - 10% of adults without children are colonized, although on military installations, as many as 50% - 60% of service personnel may be colonized. *Streptococcus pneumoniae* bacteria are spread through direct person-to-person contact with respiratory droplets released from secretions in the nose, mouth, and throat. Individuals with immunocompromising conditions (from disease or drugs), functional or anatomic asplenia (including sickle cell disease), CSF leaks, or cochlear implants are at higher risk for serious infections. In 2019, it is estimated that pneumococcal infections caused over 30,000

cases and 3,250 deaths from invasive disease (bacteremia and meningitis) in the United States.

d. Vaccine(s).

(1) Pneumococcal 13-valent conjugate vaccine (Prevnar 13® or PCV13), manufactured by Wyeth, is a sterile suspension of 13 *S. pneumoniae* serotypes individually conjugated to diphtheria CRM197 protein. Prevnar 13® was licensed in 2010 and replaced Prevnar 7®. This vaccine contains aluminum phosphate as an adjuvant (an ingredient that helps create a stronger immune response, which helps vaccines work better).

(2) Pneumococcal 15-valent conjugate vaccine (VAXNEUVANCE™ or PCV15), manufactured by Merck, is a sterile suspension of 15 *S. pneumoniae* serotypes individually conjugated to diphtheria CRM197 protein. VAXNEUVANCE™ was licensed in July 2021. This vaccine contains aluminum phosphate as an adjuvant.

(3) Pneumococcal 20-valent conjugate vaccine (Prevnar 20™ or PCV20), manufactured by Wyeth, is a sterile suspension of 20 *S. pneumoniae* serotypes individually conjugated to diphtheria CRM197 protein. Prevnar 20™ was licensed in June 2021. This vaccine contains aluminum phosphate as an adjuvant.

(4) Pneumococcal polysaccharide vaccine (Pneumovax® 23 or PPSV23), manufactured by Merck, is a sterile mixture of purified capsular polysaccharides of 23 *S. pneumoniae* serotypes. Pneumovax® 23 was licensed in 1983 and replaced a 14-serotype version licensed in 1977. The vaccine contains phenol as a preservative.

e. Contraindications and Precautions.

(1) Individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to a vaccine or any of its components should not receive that vaccine.

(2) For individuals with moderate or severe acute illness with or without fever, clinicians may administer pneumococcal vaccines if the provider and patient/parent deem the benefits of vaccination outweigh the risks.

(3) Administer pneumococcal vaccination at least 2 weeks before starting immune-suppressive therapy or elective splenectomy, if possible.

(4) For individuals with anatomic or functional asplenia and/or HIV infection, quadrivalent meningococcal conjugate vaccine (MenACWY-D, Menactra®) and pneumococcal conjugate vaccines (PCV13, PCV15, and PCV20) should not be administered simultaneously: administer the pneumococcal vaccine first and MenACWY-D 4 weeks later. This is based on immunogenicity studies that showed reduced antibody concentrations for three serotypes of pneumococcus (subtypes 4, 6B, and 18C) when pneumococcal conjugate vaccine (PCV7) was administered simultaneously with MenACWY-D.

f. Immunization.

(1) **Choice of pneumococcal vaccine for children and adolescents** (see Table 1):

a. PCV13 (Prevnar 13®) is administered as a routine four dose series given intramuscularly (IM) to all children 2 through 59 months of age: a primary series of three doses at 2, 4, and 6 months of age, and a fourth (booster) dose at 12–15 months of age. The first dose can be administered as early as 6 weeks of age. PCV13 should be administered at the same time as other routine childhood immunizations, using a separate syringe and injection site. For children vaccinated at younger than 12 months of age, the minimum interval between doses is 4 weeks. Doses given at 12 months of age and older should be separated by at least 8 weeks. Unvaccinated children 7 months of age and older do not require the full series: see the current CDC catch-up immunization schedule for recommendations.

b. PPSV23 (Pneumovax® 23) is administered as a single dose, given IM or subcutaneously (SC). The vaccine is indicated for those 2–18 years of age at high risk for invasive pneumococcal disease. PCV13 and PPSV23 should not be given at the same time. The recommended interval between PCV13 and PPSV23 for these individuals (regardless of the order in which they were received) is > 8 weeks. A second dose of PPSV23 is recommended 5 years after the first dose of PPSV23 for children who have anatomic or functional asplenia, including SCD, HIV infection, or other

immunocompromising condition. No more than 2 PPSV23 doses are recommended.

(2) **Choice of pneumococcal vaccine for adults** (see Table 2): In January 2022, ACIP issued updated recommendations for the use of pneumococcal vaccines in adults. For all individuals ≥ 65 years of age and individuals 19 - 64 years of age at high risk for invasive pneumococcal disease who have unknown or no prior adult doses of PCV13, ACIP now recommends using either PCV20 as an individual dose, or a series using PCV15 and PPSV23. Individuals ≥ 19 years of age who have already received an adult dose of PCV13 should receive a dose of PPSV23 in accordance with previous recommendations. Individuals ≥ 19 years of age who have already received an adult dose of PPSV23 (but no PCV13) should receive one dose of either PCV20 or PCV15. All Military Treatment Facilities (MTFs) and clinics should immediately add PCV15 and/or PCV20 to their formularies, and begin the transition from administering PCV13/PPSV23 to administering PCV20 or PCV15/PPSV23 to adults as outlined in these recommendations. Facilities who do not yet have PCV15 and PCV20 in stock may continue to follow previous recommendations until new vaccines are received.

a. PCV15 (VAXNEUVANCE™) is administered as a single dose, given IM. The vaccine is indicated for all individuals 65 years of age and older, and those 19 - 64 years of age at high risk for invasive pneumococcal disease. When PCV15 is used, it should be followed by a dose of PPSV23 1 year later. A minimum interval of 8 weeks between PCV15 and PPSV23 may be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak to minimize the risk of invasive pneumococcal disease caused by serotypes unique to PPSV23 in these vulnerable groups.

b. PCV20 (Prevnar 20™) is administered as a single dose, given IM. The vaccine is indicated for all individuals 65 years of age and older, and those 19 - 64 years of age at high risk for invasive pneumococcal disease. When PCV20 is used, no additional PPSV23 is recommended.

c. PPSV23 (Pneumovax® 23) is administered as a single dose, given IM or subcutaneously (SC). PPSV23 is no longer recommended for all individuals ≥ 65 years of age as described above. The vaccine is indicated for individuals ≥

65 years of age and those 19 - 64 years of age at high risk for invasive pneumococcal disease ONLY if they received PCV15 or PCV13 at least 1 year prior (or at least 8 weeks prior for certain high risk individuals).

d. PCV13 is no longer routinely recommended for adults as described above. However, according to current ACIP recommendations, the incremental public health benefits of providing PCV15 or PCV20 to adults who have received PCV13 only or both PCV13 and PPSV23 have not been evaluated. These individuals should complete the previously recommended PPSV23 series.

g. Adverse Events. The most common adverse reactions after vaccination are fever and injection site complaints such as soreness, warmth, redness, swelling, or induration. Serious allergic reactions are very rare.

h. DoD Policy. Administer pneumococcal vaccines to DoD beneficiaries as routinely indicated based on current ACIP recommendations, and to those who are in a high-risk category per ACIP recommendations or local Preventive Medicine guidance for disease outbreak prevention.

3. References.

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j. Nuorti, J., & Whitney, C. (2010). Prevention of Pneumococcal Disease among Infants and Children - Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine: Recommendations of the Advisory Committee on Immunization Practices. MMWR, 59(RR11), 1-18. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5911a1.htm.

South Atlantic Region Vaccine Safety Hub
Approved: Deputy Chief, Immunization Healthcare Division
877-438-8222 (DSN 761-4245), option 1

Table 1:

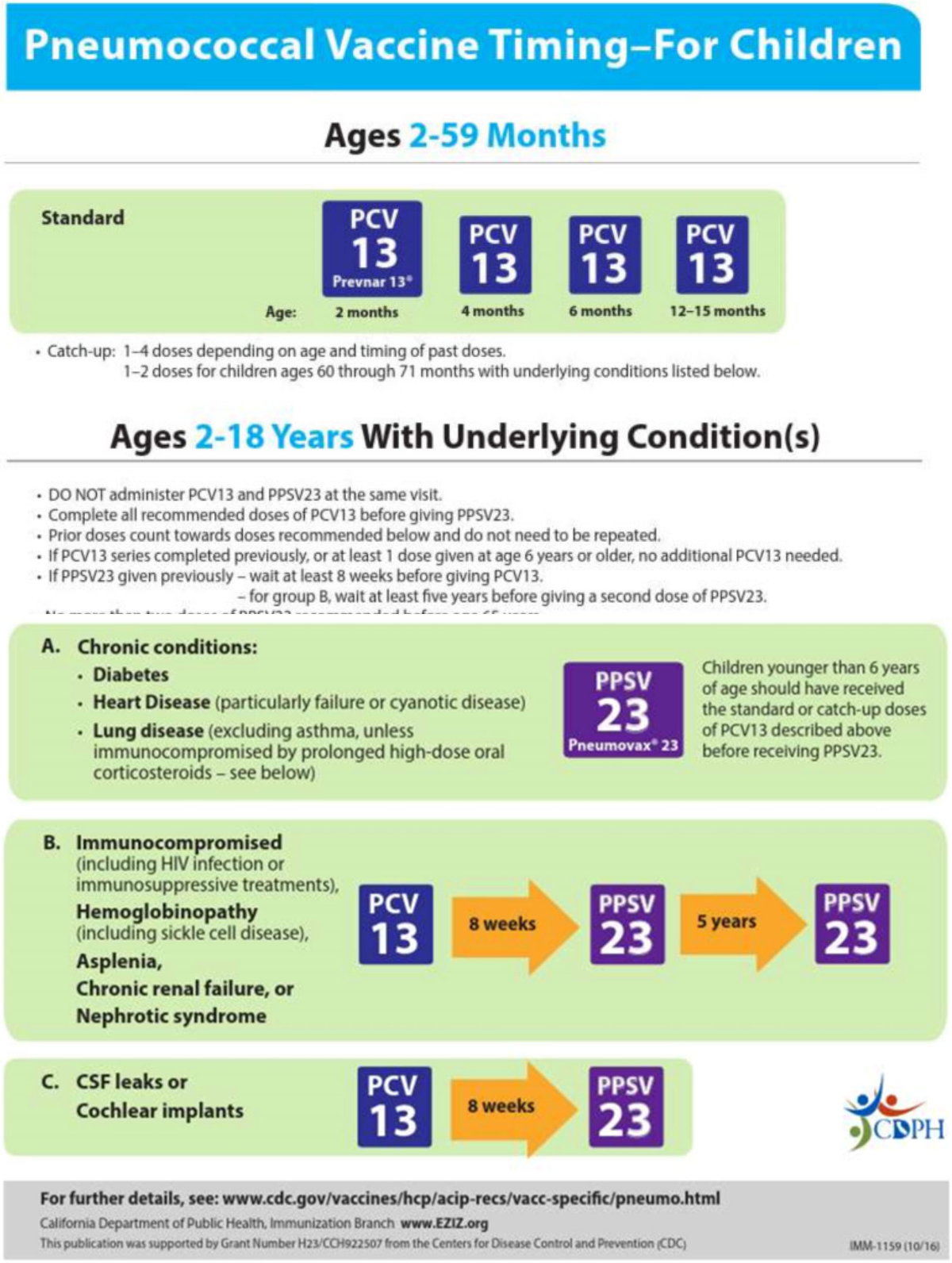
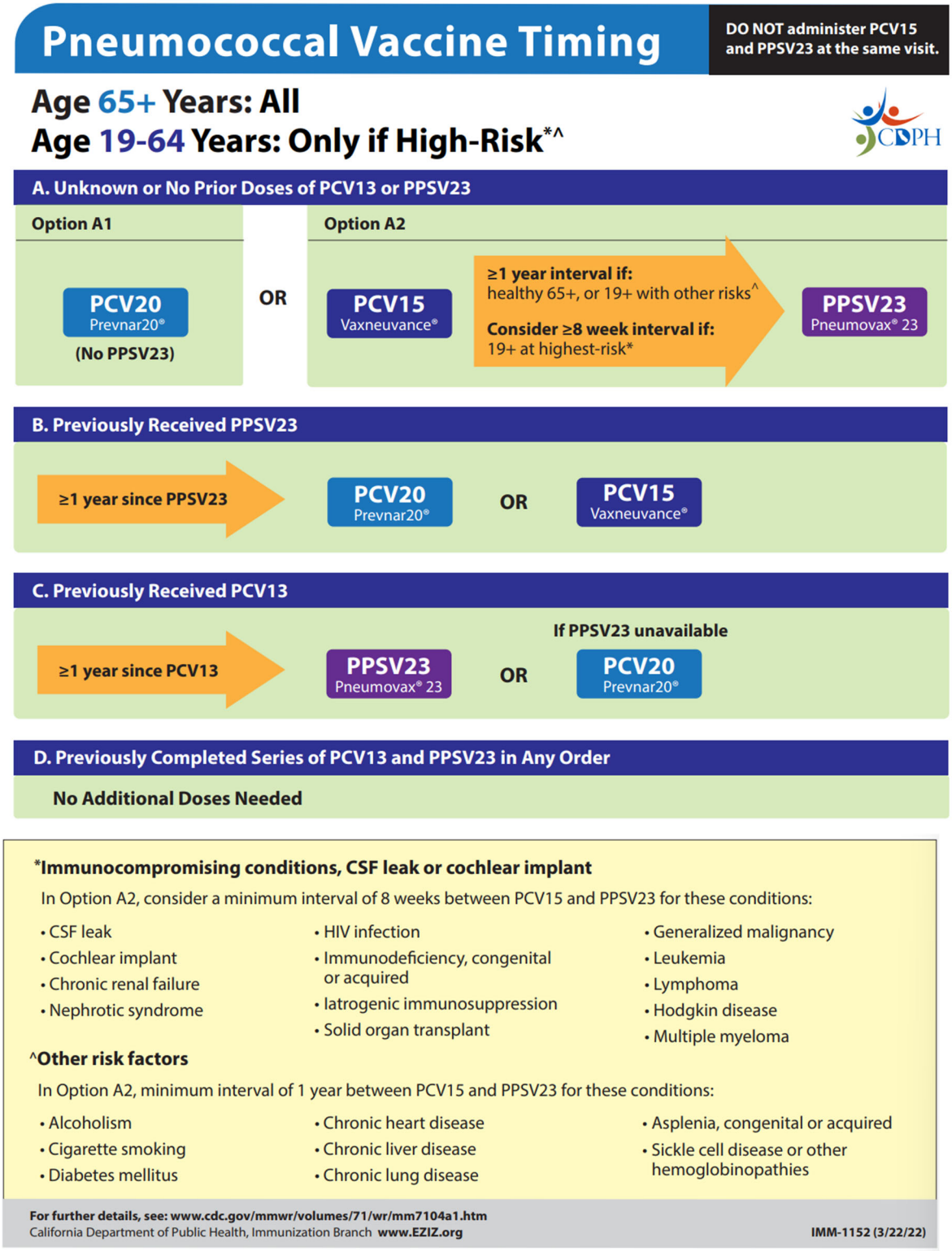

Pneumococcal Vaccine Timing–For Children
Ages 2-59 Months
Standard
PCV 13 Prevnar 13®
PCV 13
PCV 13
PCV 13
Age: 2 months
4 months
6 months
12–15 months
• Catch-up: 1–4 doses depending on age and timing of past doses.
1–2 doses for children ages 60 through 71 months with underlying conditions listed below.
Ages 2-18 Years With Underlying Condition(s)
• DO NOT administer PCV13 and PPSV23 at the same visit.
• Complete all recommended doses of PCV13 before giving PPSV23.
• Prior doses count towards doses recommended below and do not need to be repeated.
• If PCV13 series completed previously, or at least 1 dose given at age 6 years or older, no additional PCV13 needed.
• If PPSV23 given previously – wait at least 8 weeks before giving PCV13.
– for group B, wait at least five years before giving a second dose of PPSV23.
A. Chronic conditions:
• Diabetes
• Heart Disease (particularly failure or cyanotic disease)
• Lung disease (excluding asthma, unless immunocompromised by prolonged high-dose oral corticosteroids – see below)
PPSV 23 Pneumovax® 23
Children younger than 6 years of age should have received the standard or catch-up doses of PCV13 described above before receiving PPSV23.
B. Immunocompromised (including HIV infection or immunosuppressive treatments), Hemoglobinopathy (including sickle cell disease), Asplenia, Chronic renal failure, or Nephrotic syndrome
PCV 13
8 weeks
PPSV 23
5 years
PPSV 23
C. CSF leaks or Cochlear implants
PCV 13
8 weeks
PPSV 23
CDPH
For further details, see: www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/pneumo.html
California Department of Public Health, Immunization Branch www.EZIZ.org
This publication was supported by Grant Number H23/CCH922507 from the Centers for Disease Control and Prevention (CDC)
IMM-1159 (10/16)

Table 2:


Pneumococcal Vaccine Timing
DO NOT administer PCV15 and PPSV23 at the same visit.
Age 65+ Years: All
Age 19-64 Years: Only if High-Risk*^
CDPH
A. Unknown or No Prior Doses of PCV13 or PPSV23
Option A1
PCV20
Prevnar20®
(No PPSV23)
OR
Option A2
PCV15
Vaxneuvance®
≥1 year interval if:
healthy 65+, or 19+ with other risks^
Consider ≥8 week interval if:
19+ at highest-risk*
PPSV23
Pneumovax® 23
B. Previously Received PPSV23
≥1 year since PPSV23
PCV20
Prevnar20®
OR
PCV15
Vaxneuvance®
C. Previously Received PCV13
≥1 year since PCV13
PPSV23
Pneumovax® 23
OR
If PPSV23 unavailable
PCV20
Prevnar20®
D. Previously Completed Series of PCV13 and PPSV23 in Any Order
No Additional Doses Needed
*Immunocompromising conditions, CSF leak or cochlear implant
In Option A2, consider a minimum interval of 8 weeks between PCV15 and PPSV23 for these conditions:
• CSF leak
• Cochlear implant
• Chronic renal failure
• Nephrotic syndrome
• HIV infection
• Immunodeficiency, congenital or acquired
• Iatrogenic immunosuppression
• Solid organ transplant
• Generalized malignancy
• Leukemia
• Lymphoma
• Hodgkin disease
• Multiple myeloma
^Other risk factors
In Option A2, minimum interval of 1 year between PCV15 and PPSV23 for these conditions:
• Alcoholism
• Cigarette smoking
• Diabetes mellitus
• Chronic heart disease
• Chronic liver disease
• Chronic lung disease
• Asplenia, congenital or acquired
• Sickle cell disease or other hemoglobinopathies
For further details, see: www.cdc.gov/mmwr/volumes/71/wr/mm7104a1.htm
California Department of Public Health, Immunization Branch www.EZIZ.org
IMM-1152 (3/22/22)