State of California—Health and Human Services Agency
California Department of Public Health

KAREN L. SMITH, MD, MPH
Director and State Public Health Officer

GAVIN NEWSOM
Governor

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Address Block

Dear Healthcare Provider:

The California Department of Public Health (CDPH) is working with local health departments (LHD) and the Centers for Disease Control and Prevention (CDC) to investigate bacterial infections of the joints, bloodstream, and/or spine in patients who received an umbilical cord blood-derived stem cell product from the ReGen Series® (produced by Genetech and distributed by Liveyon, LLC). Your clinic has been identified as receiving shipment(s) of the ReGen Series® product and possibly administering it to patients.

Key messages:

- Serious bacterial infections associated with non-Food and Drug Administration (FDA) approved umbilical cord blood-derived stem cell products have been reported nationally and in California.
- Infections have been reported in persons who received the ReGen Series® (produced by Genetech and distributed by Liveyon, LLC) as well as other non-FDA approved umbilical cord blood-derived stem cell products not distributed by Liveyon, LLC.
- Patients should be informed of the infection risks associated with the ReGen Series® and other non-FDA approved umbilical cord blood-derived stem cell products.

Situation:

Liveyon, LLC issued a recall of the ReGen Series® product on September 28, 2018. An FDA inspection at Genetech identified significant deviations from current good manufacturing practice that increased the risk of bacterial contamination. The inspection also found deficiencies in the process for testing the umbilical cord blood donors for bloodborne pathogens, including human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV). FDA issued a warning letter to Genetech on November 29, 2019: https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm628019.htm.

In addition, bacterial infections have been reported in persons who received other non-FDA approved umbilical cord blood-derived stem cell products (not distributed by Liveyon, LLC). CDPH reminds clinicians that use of umbilical cord blood-derived stem cells to treat these types of conditions is not approved by the FDA unless an investigational new drug application (IND) is in effect. California law (Business and Professions Code Section 684) requires that clinicians inform patients in writing and with a sign posted in a prominent location in their office if they are performing non-FDA approved stem cell therapies.

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While serious bacterial infections have been linked, no HIV, HBV or HCV infections have been linked to the ReGen Series® products and transmission risk is very low. As a precaution, however, in addition to discussing the risk of bacterial infection, CDPH and LHD recommend clinicians discuss with patients who received these products whether to be tested for HIV, HBV, HCV or other communicable diseases.

The California Department of Public Health recommends that you provide patients with written notification using the attached CDPH Notice to Patients. The notice informs patients of the infection risks associated with the ReGen Series® and other umbilical cord blood-derived stem cell products. Additional information from CDC is available at: https://www.cdc.gov/hai/outbreaks/stem-cell-products.html. Your local health department will follow up with you in two to three weeks to review the status of your patient notifications.

If you have any questions or if you become aware of a patient who has had an infection related to the administration of the ReGen Series® or other stem cell product, please contact the [LHD] at [CONTACT INFO]. If you have any remaining ReGen Series® product, do not administer it to patients and contact your LHD to receive further instructions.

Sincerely,

Medical Director, Assistant Chief
Healthcare-Associated Infections Program
Center for Health Care Quality
California Department of Public Health

Enclosures: (1) CDPH Notice to Patients; (2) Suggested Cover Letter