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VERMONT DEPARTMENT OF FINANCIAL REGULATION
DIVISION OF INSURANCE

INSURANCE BULLETIN 191

BREAST TOMOSYNTHESIS

This bulletin addresses the use of breast tomosynthesis and sets forth the Department's position that insurance coverage may not be denied on the basis that this procedure is experimental or investigational. The American College of Radiology has demonstrated that regular mammography screening significantly reduces breast cancer deaths. Currently, 95 percent of mammography units in the United states are full-field digital. Breast tomosynthesis, which creates a 3-dimentional picture of the breast using X-rays, has shown to be an advance over digital mammography with higher cancer detection rates and fewer patient recalls for additional testing.

Breast tomosynthesis has been approved by the Food and Drug Administration and Medicare provides reimbursement. Breast tomosynthesis is no longer considered to be experimental or investigational and coverage cannot be denied for that reason. Vermont defines experimental or investigational in Rule H-09-03 Consumer Protections and Quality Requirements for Managed Care Organization and Rule H-2011-02 Independent External Review of Health Care Decisions as:

> "Experimental or investigational services means health care items or services that are:
>
> 1. not generally accepted by informed health care providers in the United States as effective in treating the condition or illness or diagnosis for which their use is proposed or are,
>
> 2. not proven by medical or scientific evidence to be effective in treating the condition, illness or diagnosis for which their use is proposed."

Insurers, thus, may not deny coverage for breast tomosynthesis on the grounds that the procedure is experimental or investigational.

Dated: 1/24/2017

Michael S. Pieciak, Commissioner