Specific Changes: On page BINV-6:

Change footnote gg to: The 12-gene recurrence test (EndoPredict from Myriad Genetics) can be used to identify node positive patients with very low 10-year risk of recurrence for whom chemotherapy may be unnecessary.

Rationale: The footnote presently endorses use of the 21-gene RT-PCR assay (Oncotype Dx from Genomic Health) for risk assessment in this patient population; however, low risk patients identified with this assay have a 19-40% risk of recurrence. EndoPredict’s EPclin score identifies node positive patients that are truly low risk, shown to have a 10-year risk of recurrence of 5.0%. The rate for EPclin low risk patients with node positive disease is thus lower than that for node negative RS-low patients (5.9%), for whom the panel currently recommends endocrine therapy only. These new data support rewording the footnote so that oncologists are aware of the opportunity to identify node positive patients with exceedingly low 10-year risk of recurrence and who may have good outcomes with endocrine therapy only.
References


Sincerely,

[Signature]

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