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<Citation id="1" source="inferred">Burstein HJ, Prestrud AA, Seidenfeld J, Anderson H, Buchholz TA, Davidson NE, Gelmon KE, Giordano SH, Hudis CA, Malin J, Mamounas EP, Rowden D, Solky AJ, Sowers MR, Stearns V, Winer EP, Somerfield MR, Griggs JJ, American Society of Clinical Oncology. American Society of Clinical Oncology clinical practice guideline: update on adjuvant endocrine therapy for women with hormone receptor-positive breast cancer. J Clin Oncol 2010 Aug 10;28(23):3784-96. [124 references]<GuidelineLength id="1" source="nd"/>

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<GEMCutDate id="1" source="inferred">October 2012</GEMCutDate>

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<ReleaseDate id="1" source="inferred">August 2010</ReleaseDate>

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<DeveloperName id="1" source="inferred">American Society of Clinical Oncology</DeveloperName>

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<InclusionCriterion id="1" source="inferred">postmenopausal women with hormone receptor–positive breast cancer<InclusionCriterionCode id="1" source="nd"/>

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</Eligibility>

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<KnowledgeComponents id="1" source="nd">

<Recommendation id="1" source="inferred">1<StatementOfFact id="1" source="nd"/>

<Conditional id="15" source="inferred">The Update Committee recommends,

on the basis of data from randomized, controlled trials, that most postmenopausal women consider taking an AI during the course of adjuvant treatment to lower recurrence risk, either as primary therapy or after 2 to 3 years of tamoxifen—strategies that yield equivalent outcomes in prospective studies. Duration of AI therapy should not exceed 5 years.<BenefitHarmAssessment id="24" source="nd"/>

<DecisionVariable id="31" source="inferred">postmenopausal<Value id="32" source="inferred">true</Value>

<DecisionVariableCode id="31" source="nd"/>

<DecisionVariableDescription id="31" source="nd">

<IntentionalVagueness id="56" source="nd"/>

</DecisionVariableDescription>

<TestParameter id="31" source="nd">

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<Specificity id="31" source="nd"/>

<PredictiveValue id="31" source="nd"/>

</TestParameter>

<DecisionVariableCost id="31" source="nd"/>

</DecisionVariable>

<DecisionVariable id="40" source="inferred">adjuvant treatment<Value id="41" source="inferred">true</Value>

<DecisionVariableCode codeset="" id="40" source="nd"/>

<DecisionVariableDescription id="40" source="nd">

<IntentionalVagueness id="70" source="nd"/>

</DecisionVariableDescription>

<TestParameter id="40" source="nd">

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<PredictiveValue id="40" source="nd"/>

</TestParameter>

<DecisionVariableCost id="40" source="nd"/>

</DecisionVariable>

<DecisionVariable id="41" source="inferred">tamoxifen use<Value id="42" source="inferred">2-3 years</Value>

<DecisionVariableCode id="41" source="nd"/>

<DecisionVariableDescription id="41" source="nd">

<IntentionalVagueness id="71" source="nd"/>

</DecisionVariableDescription>

<TestParameter id="41" source="nd">

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<Specificity id="41" source="nd"/>

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<DecisionVariableCost id="41" source="nd"/>

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<Action id="17" source="inferred">Consider taking an AI<ActionActor id="17" source="nd"/>

<ActionCode codeset="" id="17" source="nd"/>

<ActionVerb id="17" source="nd"/>

<ActionDeonticTerm id="17" source="nd"/>

<ActionVerbComplement id="17" source="nd"/>

<ActionBenefit id="17" source="nd"/>

<ActionRiskHarm id="17" source="nd"/>

<ActionDescription id="17" source="inferred">Duration of AI therapy should not exceed 5 years<IntentionalVagueness id="57" source="nd"/>

</ActionDescription>

<ActionCost id="17" source="nd"/>

<ActionValue id="17" source="nd"/>

<ActionType id="17" source="nd"/>

</Action>

<Reason id="35" source="inferred">In comparison to 5 years of tamoxifen alone, use of an AI in either primary, sequential, or extended treatment improves disease-free survival and reduces the risk of breast cancer events, including distant recurrence, locoregional recurrence, and contralateral breast cancer</Reason>

<Reason id="39" source="inferred">Breast cancer events such as locoregional recurrence, contralateral breast cancer, and early distant metastatic recurrence are clinically important to patients. For this reason, the Update Committee recommended consideration of AI therapy at some time during adjuvant endocrine therapy even though few trials demonstrated statistically significant differences in overall survival.</Reason>

<EvidenceQuality id="24" source="nd">

<EvidenceQualityDescription id="24" source="nd"/>

<Disagreement id="24" source="nd"/>

</EvidenceQuality>

<RecommendationStrength id="24" source="nd">

<RecommendationStrengthCode id="24" source="nd"/>

</RecommendationStrength>

<Flexibility id="24" source="nd"/>

<Logic id="24" source="inferred">If &#13;

postmenopausal is [true] &#13;&#13;

AND&#13;&#13;

adjuvant treatment is [true] &#13;&#13;

AND&#13;&#13;

tamoxifen use is [2-3 years] &#13;

Then &#13;

Consider taking an AI</Logic>

<Cost id="24" source="nd"/>

<Linkage id="24" source="nd"/>

<Reference id="24" source="nd"/>

<Certainty id="24" source="nd"/>

<Goal id="24" source="nd"/>

</Conditional>

<Conditional id="14" source="inferred">The Update Committee recommends,

on the basis of data from randomized, controlled trials, that most postmenopausal women consider taking an AI during the course of adjuvant treatment to lower recurrence risk, either as primary therapy or after 2 to 3 years of tamoxifen—strategies that yield equivalent outcomes in prospective studies. Duration of AI therapy should not exceed 5 years.<BenefitHarmAssessment id="23" source="nd"/>

<DecisionVariable id="30" source="inferred">postmenopausal<Value id="31" source="inferred">true</Value>

<DecisionVariableCode id="30" source="nd"/>

<DecisionVariableDescription id="30" source="nd">

<IntentionalVagueness id="54" source="nd"/>

</DecisionVariableDescription>

<TestParameter id="30" source="nd">

<Sensitivity id="30" source="nd"/>

<Specificity id="30" source="nd"/>

<PredictiveValue id="30" source="nd"/>

</TestParameter>

<DecisionVariableCost id="30" source="nd"/>

</DecisionVariable>

<DecisionVariable id="38" source="inferred">adjuvant treatment<Value id="39" source="inferred">true</Value>

<DecisionVariableCode id="38" source="nd"/>

<DecisionVariableDescription id="38" source="nd">

<IntentionalVagueness id="68" source="nd"/>

</DecisionVariableDescription>

<TestParameter id="38" source="nd">

<Sensitivity id="38" source="nd"/>

<Specificity id="38" source="nd"/>

<PredictiveValue id="38" source="nd"/>

</TestParameter>

<DecisionVariableCost id="38" source="nd"/>

</DecisionVariable>

<DecisionVariable id="39" source="inferred">tamoxifen use<Value id="40" source="inferred">false</Value>

<DecisionVariableCode id="39" source="nd"/>

<DecisionVariableDescription id="39" source="nd">

<IntentionalVagueness id="69" source="nd"/>

</DecisionVariableDescription>

<TestParameter id="39" source="nd">

<Sensitivity id="39" source="nd"/>

<Specificity id="39" source="nd"/>

<PredictiveValue id="39" source="nd"/>

</TestParameter>

<DecisionVariableCost id="39" source="nd"/>

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<Action id="16" source="inferred">consider taking an AI<ActionActor id="16" source="nd"/>

<ActionCode id="16" source="nd"/>

<ActionVerb id="16" source="nd"/>

<ActionDeonticTerm id="16" source="nd"/>

<ActionVerbComplement id="16" source="nd"/>

<ActionBenefit id="16" source="nd"/>

<ActionRiskHarm id="16" source="nd"/>

<ActionDescription id="16" source="inferred">Duration of AI therapy should not exceed 5 years.<IntentionalVagueness id="55" source="nd"/>

</ActionDescription>

<ActionCost id="16" source="nd"/>

<ActionValue id="16" source="nd"/>

<ActionType id="16" source="nd"/>

</Action>

<Reason id="34" source="inferred">In comparison to 5 years of tamoxifen alone, use of an AI in either primary, sequential, or extended treatment improves disease-free survival and reduces the risk of breast cancer events, including distant recurrence, locoregional recurrence, and contralateral breast cancer</Reason>

<Reason id="38" source="inferred">Breast cancer events such as locoregional recurrence, contralateral breast cancer, and early distant metastatic recurrence are clinically important to patients. For this reason, the Update Committee recommended consideration of AI therapy at some time during adjuvant endocrine therapy even though few trials demonstrated statistically significant differences in overall survival.</Reason>

<EvidenceQuality id="23" source="nd">

<EvidenceQualityDescription id="23" source="nd"/>

<Disagreement id="23" source="nd"/>

</EvidenceQuality>

<RecommendationStrength id="23" source="nd">

<RecommendationStrengthCode id="23" source="nd"/>

</RecommendationStrength>

<Flexibility id="23" source="nd"/>

<Logic id="23" source="inferred">If &#13;

postmenopausal is [true] &#13;&#13;

AND&#13;&#13;

adjuvant treatment is [true] &#13;&#13;

AND&#13;&#13;

tamoxifen use is [false] &#13;

Then &#13;

consider taking an AI</Logic>

<Cost id="23" source="nd"/>

<Linkage id="23" source="nd"/>

<Reference id="23" source="nd"/>

<Certainty id="23" source="nd"/>

<Goal id="23" source="nd"/>

</Conditional>

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<BenefitHarmAssessment id="1" source="nd"/>

<Scope id="1" source="inferred">

<ScopeCode id="1" source="nd"/>

</Scope>

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<DirectiveBenefit id="1" source="nd"/>

<DirectiveRiskHarm id="1" source="nd"/>

<DirectiveDescription id="1" source="nd">

<IntentionalVagueness id="1" source="nd"/>

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<Certainty id="1" source="nd"/>

<Goal id="1" source="nd"/>

</Imperative>

<RecommendationNotes id="1" source="inferred">SCENARIO 4</RecommendationNotes>

<RecommendationNotes id="9" source="inferred"/>

</Recommendation>

<Recommendation id="4" source="inferred">2<StatementOfFact id="4" source="nd"/>

<Conditional id="7" source="inferred">The Update Committee recommends that patients who are initially treated with an AI but discontinue treatment before 5 years of

therapy consider taking tamoxifen for a total of 5 years of adjuvant endocrine therapy.<BenefitHarmAssessment id="12" source="nd"/>

<DecisionVariable id="8" source="inferred">AI<Value id="8" source="inferred">true</Value>

<DecisionVariableCode codeset="" id="8" source="nd"/>

<DecisionVariableDescription id="8" source="nd">

<IntentionalVagueness id="20" source="nd"/>

</DecisionVariableDescription>

<TestParameter id="8" source="nd">

<Sensitivity id="8" source="nd"/>

<Specificity id="8" source="nd"/>

<PredictiveValue id="8" source="nd"/>

</TestParameter>

<DecisionVariableCost id="8" source="nd"/>

</DecisionVariable>

<DecisionVariable id="37" source="inferred">tamoxifen<Value id="38" source="inferred">false</Value>

<DecisionVariableCode id="37" source="nd"/>

<DecisionVariableDescription id="37" source="nd">

<IntentionalVagueness id="67" source="nd"/>

</DecisionVariableDescription>

<TestParameter id="37" source="nd">

<Sensitivity id="37" source="nd"/>

<Specificity id="37" source="nd"/>

<PredictiveValue id="37" source="nd"/>

</TestParameter>

<DecisionVariableCost id="37" source="nd"/>

</DecisionVariable>

<Action id="8" source="inferred">consider tamoxifen for a duration of (5 years minus AI duration) years<ActionActor id="8" source="nd"/>

<ActionCode id="8" source="nd"/>

<ActionVerb id="8" source="nd"/>

<ActionDeonticTerm id="8" source="nd"/>

<ActionVerbComplement id="8" source="nd"/>

<ActionBenefit id="8" source="nd"/>

<ActionRiskHarm id="8" source="nd"/>

<ActionDescription id="8" source="nd">

<IntentionalVagueness id="21" source="nd"/>

</ActionDescription>

<ActionCost id="8" source="nd"/>

<ActionValue id="8" source="nd"/>

<ActionType id="8" source="nd"/>

</Action>

<Reason id="14" source="inferred">The treatment regimen for patients in the sequencing trials spanned 5 years. No data support clinical benefits for durations of AIs

longer than 2 or 3 years in a sequencing strategy.</Reason>

<Reason id="33" source="inferred">Data from randomized, controlled trials demonstrate that women who receive primary AI therapy should be treated for a total of 5 years.</Reason>

<EvidenceQuality id="12" source="nd">

<EvidenceQualityDescription id="12" source="nd"/>

<Disagreement id="12" source="nd"/>

</EvidenceQuality>

<RecommendationStrength id="12" source="nd">

<RecommendationStrengthCode id="12" source="nd"/>

</RecommendationStrength>

<Flexibility id="12" source="nd"/>

<Logic id="12" source="inferred">If &#13;

AI is [true] &#13;&#13;

AND&#13;&#13;

tamoxifen is [false] &#13;

Then &#13;

consider tamoxifen for a duration of (5 years minus AI duration) years</Logic>

<Cost id="12" source="nd"/>

<Linkage id="12" source="nd"/>

<Reference id="12" source="nd"/>

<Certainty id="12" source="nd"/>

<Goal id="12" source="nd"/>

</Conditional>

<Conditional id="9" source="inferred">Therapy with an AI should not extend beyond 5 years in either the primary or extended adjuvant settings outside the clinical trials setting.<BenefitHarmAssessment id="14" source="inferred"/>

<DecisionVariable id="13" source="inferred">in the primary setting<Value id="13" source="inferred">true</Value>

<DecisionVariableCode id="13" source="nd"/>

<DecisionVariableDescription id="13" source="nd">

<IntentionalVagueness id="27" source="nd"/>

</DecisionVariableDescription>

<TestParameter id="13" source="nd">

<Sensitivity id="13" source="nd"/>

<Specificity id="13" source="nd"/>

<PredictiveValue id="13" source="nd"/>

</TestParameter>

<DecisionVariableCost id="13" source="nd"/>

</DecisionVariable>

<DecisionVariable id="14" source="inferred">in the extended adjuvant setting<Value id="14" source="inferred">true</Value>

<Value id="15" source="nd"/>

<DecisionVariableCode id="14" source="nd"/>

<DecisionVariableDescription id="14" source="nd">

<IntentionalVagueness id="29" source="nd"/>

</DecisionVariableDescription>

<TestParameter id="14" source="nd">

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<PredictiveValue id="14" source="nd"/>

</TestParameter>

<DecisionVariableCost id="14" source="nd"/>

</DecisionVariable>

<DecisionVariable id="15" source="inferred">in a AI clinical trial<Value id="16" source="inferred">false</Value>

<DecisionVariableCode id="15" source="nd"/>

<DecisionVariableDescription id="15" source="nd">

<IntentionalVagueness id="30" source="nd"/>

</DecisionVariableDescription>

<TestParameter id="15" source="nd">

<Sensitivity id="15" source="nd"/>

<Specificity id="15" source="nd"/>

<PredictiveValue id="15" source="nd"/>

</TestParameter>

<DecisionVariableCost id="15" source="nd"/>

</DecisionVariable>

<DecisionVariable id="34" source="inferred">AI use<Value id="35" source="inferred"/>

<DecisionVariableCode id="34" source="nd"/>

<DecisionVariableDescription id="34" source="nd">

<IntentionalVagueness id="64" source="nd"/>

</DecisionVariableDescription>

<TestParameter id="34" source="nd">

<Sensitivity id="34" source="nd"/>

<Specificity id="34" source="nd"/>

<PredictiveValue id="34" source="nd"/>

</TestParameter>

<DecisionVariableCost id="34" source="nd"/>

</DecisionVariable>

<DecisionVariable id="35" source="inferred">tamoxifen use<Value id="36" source="inferred">2-3 years</Value>

<DecisionVariableCode codeset="" id="35" source="nd"/>

<DecisionVariableDescription id="35" source="nd">

<IntentionalVagueness id="65" source="nd"/>

</DecisionVariableDescription>

<TestParameter id="35" source="nd">

<Sensitivity id="35" source="nd"/>

<Specificity id="35" source="nd"/>

<PredictiveValue id="35" source="nd"/>

</TestParameter>

<DecisionVariableCost id="35" source="nd"/>

</DecisionVariable>

<Action id="10" source="inferred">discontinue AI after 5 years total endocrine therapy<ActionActor id="10" source="nd"/>

<ActionCode id="10" source="nd"/>

<ActionVerb id="10" source="nd"/>

<ActionDeonticTerm id="10" source="nd"/>

<ActionVerbComplement id="10" source="nd"/>

<ActionBenefit id="10" source="nd"/>

<ActionRiskHarm id="10" source="nd"/>

<ActionDescription id="10" source="nd">

<IntentionalVagueness id="28" source="nd"/>

</ActionDescription>

<ActionCost id="10" source="nd"/>

<ActionValue id="10" source="nd"/>

<ActionType id="10" source="nd"/>

</Action>

<Reason id="16" source="inferred">Safety and efficacy data from the primary trials support up to 5 years of AI therapy as a primary adjuvant strategy, a duration used in two trials of extended therapy after 5 years of tamoxifen.</Reason>

<Reason id="17" source="inferred"/>

<EvidenceQuality id="14" source="nd">

<EvidenceQualityDescription id="14" source="nd"/>

<Disagreement id="14" source="nd"/>

</EvidenceQuality>

<RecommendationStrength id="14" source="nd">

<RecommendationStrengthCode id="14" source="nd"/>

</RecommendationStrength>

<Flexibility id="14" source="nd"/>

<Logic id="14" source="inferred">If &#13;

(in the primary setting is [true] &#13;

OR&#13;

in the extended adjuvant setting is [true] ) &#13;

AND&#13;

in the clinical trials setting is [false] &#13;

AND &#13;&#13;

(AI use&#13;&#13;

OR&#13;&#13;

tamoxifen use is [2-3 years] ) &#13;

Then &#13;

discontinue AI after 5 years total endocrine therapy</Logic>

<Cost id="14" source="nd"/>

<Linkage id="14" source="nd"/>

<Reference id="14" source="nd"/>

<Certainty id="14" source="nd"/>

<Goal id="14" source="nd"/>

</Conditional>

<Imperative id="4" source="explicit">

<BenefitHarmAssessment id="8" source="nd"/>

<Scope id="4" source="explicit">

<ScopeCode id="4" source="nd"/>

</Scope>

<Directive id="4" source="explicit">

<DirectiveActor id="4" source="nd"/>

<DirectiveCode id="4" source="nd"/>

<DirectiveVerb id="4" source="nd"/>

<DirectiveDeonticTerm id="4" source="nd"/>

<DirectiveVerbComplement id="4" source="nd"/>

<DirectiveBenefit id="4" source="nd"/>

<DirectiveRiskHarm id="4" source="nd"/>

<DirectiveDescription id="4" source="nd">

<IntentionalVagueness id="12" source="nd"/>

</DirectiveDescription>

<DirectiveCost id="4" source="nd"/>

<DirectiveValue id="4" source="nd"/>

<DirectiveType id="4" source="nd"/>

</Directive>

<Reason id="8" source="explicit"/>

<EvidenceQuality id="8" source="nd">

<EvidenceQualityDescription id="8" source="nd"/>

<Disagreement id="8" source="nd"/>

</EvidenceQuality>

<RecommendationStrength id="8" source="nd">

<RecommendationStrengthCode id="8" source="nd"/>

</RecommendationStrength>

<Flexibility id="8" source="nd"/>

<Logic id="8" source="nd"/>

<Cost id="8" source="nd"/>

<Linkage id="8" source="nd"/>

<Reference id="8" source="nd"/>

<Certainty id="8" source="nd"/>

<Goal id="8" source="nd"/>

</Imperative>

<RecommendationNotes id="4" source="inferred">SCENARIO 4</RecommendationNotes>

</Recommendation>

<Recommendation id="1" source="inferred">3<StatementOfFact id="1" source="nd"/>

<Conditional id="1" source="inferred">The Update Committee recommends that

women who are pre- or perimenopausal at the time of breast cancer diagnosis be treated with 5 years of tamoxifen.<BenefitHarmAssessment id="1" source="nd"/>

<DecisionVariable id="1" source="inferred">not menopausal<Value id="1" source="nd"/>

<DecisionVariableCode id="1" source="nd"/>

<DecisionVariableDescription id="1" source="inferred">at the time of diagnosis<IntentionalVagueness id="1" source="nd"/>

</DecisionVariableDescription>

<TestParameter id="1" source="nd">

<Sensitivity id="1" source="nd"/>

<Specificity id="1" source="nd"/>

<PredictiveValue id="1" source="nd"/>

</TestParameter>

<DecisionVariableCost id="1" source="nd"/>

</DecisionVariable>

<DecisionVariable id="24" source="inferred">treatment-induced amenorrhea<Value id="25" source="nd"/>

<DecisionVariableCode id="24" source="nd"/>

<DecisionVariableDescription id="24" source="nd">

<IntentionalVagueness id="41" source="nd"/>

</DecisionVariableDescription>

<TestParameter id="24" source="nd">

<Sensitivity id="24" source="nd"/>

<Specificity id="24" source="nd"/>

<PredictiveValue id="24" source="nd"/>

</TestParameter>

<DecisionVariableCost id="24" source="nd"/>

</DecisionVariable>

<Action id="1" source="inferred">treat with 5 years of tamoxifen as primary adjuvant endocrine therapy<ActionActor id="1" source="nd"/>

<ActionCode id="1" source="nd"/>

<ActionVerb id="1" source="nd"/>

<ActionDeonticTerm id="1" source="nd"/>

<ActionVerbComplement id="1" source="nd"/>

<ActionBenefit id="1" source="nd"/>

<ActionRiskHarm id="1" source="nd"/>

<ActionDescription id="1" source="inferred">The Update Committee recommends

that clinicians use caution in evaluating menopausal status of patients who were pre- or perimenopausal at diagnosis. Unequivocal determination of menopausal status may be challenging to prove.

Even among women who have not experienced menses for more than

1 year, laboratory testing is inadequate because patients may recover

ovarian function. This particularly applies to those patients who experience

chemotherapy- or tamoxifen-induced amenorrhea.<IntentionalVagueness id="2" source="nd"/>

</ActionDescription>

<ActionCost id="1" source="nd"/>

<ActionValue id="1" source="nd"/>

<ActionType id="1" source="nd"/>

</Action>

<Reason id="1" source="inferred">AI therapy has been shown to

be effective only in postmenopausal women and is contraindicated in patients with residual ovarian function. Patients accrued to ABCSG-12, the only trial to include premenopausal women, were all treated

with gonadotropin-releasing hormone agonist therapy to achieve a

postmenopausal state. Eligible patients had favorable prognosis and low-grade breast cancer, and none received adjuvant chemotherapy, though 5% did receive neoadjuvant chemotherapy. These patients are not necessarily representative of younger women with early-stage breast cancer. ABCSG-12 demonstrated equivalence with respect to time to recurrence, disease-free survival, and overall survival between tamoxifen and AI therapy in premenopausal women given ovarian suppression. Because of tamoxifen equivalence with AI therapy in that setting and the occasional failure to achieve menopausal status with ovarian uppression, the Update Committee strongly recommends tamoxifen as primary adjuvant endocrine therapy for all pre- or perimenopausal women and women with treatment-induced amenorrhea.</Reason>

<EvidenceQuality id="1" source="nd">

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<Disagreement id="1" source="nd"/>

</EvidenceQuality>

<RecommendationStrength id="1" source="nd">

<RecommendationStrengthCode id="1" source="nd"/>

</RecommendationStrength>

<Flexibility id="1" source="nd"/>

<Logic id="1" source="inferred">If &#13;

not menopausal&#13;

OR&#13;

treatment-induced amenorrhea&#13;

Then &#13;

treat with 5 years of tamoxifen as primary adjuvant endocrine therapy</Logic>

<Cost id="1" source="nd"/>

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</Recommendation>

<Recommendation id="6" source="inferred">4<StatementOfFact id="6" source="nd"/>

<Conditional id="12" source="inferred">The Update Committee suggests that clinicians consider recommending

that patients change treatment if adverse effects are intolerable or if patients are persistently noncompliant with therapy<BenefitHarmAssessment id="17" source="nd"/>

<DecisionVariable id="25" source="inferred">adverse effects are intolerable<Value id="26" source="nd"/>

<DecisionVariableCode id="25" source="nd"/>

<DecisionVariableDescription id="25" source="nd">

<IntentionalVagueness id="42" source="nd"/>

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</TestParameter>

<DecisionVariableCost id="25" source="nd"/>

</DecisionVariable>

<DecisionVariable id="26" source="inferred">persistently noncompliant with therapy<Value id="27" source="nd"/>

<DecisionVariableCode id="26" source="nd"/>

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<IntentionalVagueness id="47" source="nd"/>

</DecisionVariableDescription>

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<Action id="13" source="inferred">clinicians may recommend that patients change treatment<ActionActor id="13" source="nd"/>

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<EvidenceQuality id="17" source="nd">

<EvidenceQualityDescription id="17" source="nd"/>

<Disagreement id="17" source="nd"/>

</EvidenceQuality>

<RecommendationStrength id="17" source="nd">

<RecommendationStrengthCode id="17" source="nd"/>

</RecommendationStrength>

<Flexibility id="17" source="nd"/>

<Logic id="17" source="inferred">If &#13;

adverse effects are intolerable&#13;

OR&#13;

persistently noncompliant with therapy&#13;

Then &#13;

clinicians may recommend that patients change treatment</Logic>

<Cost id="17" source="nd"/>

<Linkage id="17" source="nd"/>

<Reference id="17" source="nd"/>

<Certainty id="17" source="nd"/>

<Goal id="17" source="nd"/>

</Conditional>

<Conditional id="16" source="inferred">The Update Committee recommends that

clinicians consider adverse effect profiles, patient preferences, and pre-existing conditions when recommending an adjuvant endocrine strategy for postmenopausal women.<BenefitHarmAssessment id="25" source="nd"/>

<DecisionVariable id="32" source="inferred">recommending adjuvant endocrine therapy<Value id="33" source="nd"/>

<DecisionVariableCode id="32" source="nd"/>

<DecisionVariableDescription id="32" source="nd">

<IntentionalVagueness id="58" source="nd"/>

</DecisionVariableDescription>

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<PredictiveValue id="32" source="nd"/>

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<Action id="18" source="inferred">consider adverse effects<ActionActor id="18" source="nd"/>

<ActionCode id="18" source="nd"/>

<ActionVerb id="18" source="nd"/>

<ActionDeonticTerm id="18" source="nd"/>

<ActionVerbComplement id="18" source="nd"/>

<ActionBenefit id="18" source="nd"/>

<ActionRiskHarm id="18" source="nd"/>

<ActionDescription id="18" source="nd">

<IntentionalVagueness id="59" source="nd"/>

</ActionDescription>

<ActionCost id="18" source="nd"/>

<ActionValue id="18" source="nd"/>

<ActionType id="18" source="nd"/>

</Action>

<Action id="19" source="inferred">consider patient preferences<ActionActor id="19" source="nd"/>

<ActionCode id="19" source="nd"/>

<ActionVerb id="19" source="nd"/>

<ActionDeonticTerm id="19" source="nd"/>

<ActionVerbComplement id="19" source="nd"/>

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</ActionDescription>

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<ActionType id="19" source="nd"/>

</Action>

<Action id="20" source="inferred">consider pre-existing conditions<ActionActor id="20" source="nd"/>

<ActionCode id="20" source="nd"/>

<ActionVerb id="20" source="nd"/>

<ActionDeonticTerm id="20" source="nd"/>

<ActionVerbComplement id="20" source="nd"/>

<ActionBenefit id="20" source="nd"/>

<ActionRiskHarm id="20" source="nd"/>

<ActionDescription id="20" source="nd">

<IntentionalVagueness id="61" source="nd"/>

</ActionDescription>

<ActionCost id="20" source="nd"/>

<ActionValue id="20" source="nd"/>

<ActionType id="20" source="nd"/>

</Action>

<Reason id="36" source="nd"/>

<EvidenceQuality id="25" source="nd">

<EvidenceQualityDescription id="25" source="nd"/>

<Disagreement id="25" source="nd"/>

</EvidenceQuality>

<RecommendationStrength id="25" source="nd">

<RecommendationStrengthCode id="25" source="nd"/>

</RecommendationStrength>

<Flexibility id="25" source="nd"/>

<Logic id="25" source="inferred">If &#13;

recommending adjuvant endocrine therapy&#13;

Then &#13;

consider adverse effects&#13;&#13;

AND&#13;&#13;

consider patient preferences&#13;&#13;

AND&#13;&#13;

consider pre-existing conditions</Logic>

<Cost id="25" source="nd"/>

<Linkage id="25" source="nd"/>

<Reference id="25" source="nd"/>

<Certainty id="25" source="nd"/>

<Goal id="25" source="nd"/>

</Conditional>

<Conditional id="17" source="inferred">Clinicians should discuss adverse effect profiles when presenting available treatment options.<BenefitHarmAssessment id="26" source="nd"/>

<DecisionVariable id="33" source="inferred">Recommending adjuvant endocrine therapy<Value id="34" source="nd"/>

<DecisionVariableCode id="33" source="nd"/>

<DecisionVariableDescription id="33" source="nd">

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<PredictiveValue id="33" source="nd"/>

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<Action id="21" source="inferred">counsel about adverse effect profiles of tamoxifen and AI<ActionActor id="21" source="nd"/>

<ActionCode id="21" source="nd"/>

<ActionVerb id="21" source="nd"/>

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<ActionVerbComplement id="21" source="nd"/>

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<ActionRiskHarm id="21" source="nd"/>

<ActionDescription id="21" source="nd">

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<Disagreement id="26" source="nd"/>

</EvidenceQuality>

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<RecommendationStrengthCode id="26" source="nd"/>

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<Flexibility id="26" source="nd"/>

<Logic id="26" source="inferred">If &#13;

Recommending adjuvant endocrine therapy&#13;

Then &#13;

counsel about adverse effect profiles of tamoxifen and AI</Logic>

<Cost id="26" source="nd"/>

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<DirectiveVerbComplement id="8" source="nd"/>

<DirectiveBenefit id="8" source="nd"/>

<DirectiveRiskHarm id="8" source="nd"/>

<DirectiveDescription id="8" source="nd">

<IntentionalVagueness id="46" source="nd"/>

</DirectiveDescription>

<DirectiveCost id="8" source="nd"/>

<DirectiveValue id="8" source="nd"/>

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<RecommendationNotes id="6" source="inferred">SCENARIO 4</RecommendationNotes>

<RecommendationNotes id="8" source="inferred"/>

</Recommendation>

<Recommendation id="7" source="inferred">5<StatementOfFact id="7" source="nd"/>

<Conditional id="13" source="inferred">In the clinical opinion of the Update Committee (rather than direct evidence from randomized trials), postmenopausal patients intolerant of one AI but who are still candidates for adjuvant endocrine therapy may be advised to consider tamoxifen or a different AI.<BenefitHarmAssessment id="21" source="nd"/>

<DecisionVariable id="27" source="inferred">postmenopausal<Value id="28" source="nd"/>

<DecisionVariableCode id="27" source="nd"/>

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<PredictiveValue id="27" source="nd"/>

</TestParameter>

<DecisionVariableCost id="27" source="nd"/>

</DecisionVariable>

<DecisionVariable id="29" source="inferred">intolerant of one AI<Value id="30" source="nd"/>

<DecisionVariableCode id="29" source="nd"/>

<DecisionVariableDescription id="29" source="nd">

<IntentionalVagueness id="52" source="nd"/>

</DecisionVariableDescription>

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<PredictiveValue id="29" source="nd"/>

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<DecisionVariableCost id="29" source="nd"/>

</DecisionVariable>

<DecisionVariable id="28" source="inferred">still candidate for adjuvant endocrine therapy<Value id="29" source="nd"/>

<DecisionVariableCode id="28" source="nd"/>

<DecisionVariableDescription id="28" source="nd">

<IntentionalVagueness id="51" source="nd"/>

</DecisionVariableDescription>

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<Action id="14" source="inferred">may be advised to consider tamoxifen<ActionActor id="14" source="nd"/>

<ActionCode id="14" source="nd"/>

<ActionVerb id="14" source="nd"/>

<ActionDeonticTerm id="14" source="nd"/>

<ActionVerbComplement id="14" source="nd"/>

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</ActionDescription>

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<ActionType id="14" source="nd"/>

</Action>

<Action id="15" source="inferred">may be advised to consider a different AI<ActionActor id="15" source="nd"/>

<ActionCode id="15" source="nd"/>

<ActionVerb id="15" source="nd"/>

<ActionDeonticTerm id="15" source="nd"/>

<ActionVerbComplement id="15" source="nd"/>

<ActionBenefit id="15" source="nd"/>

<ActionRiskHarm id="15" source="nd"/>

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</ActionDescription>

<ActionCost id="15" source="nd"/>

<ActionValue id="15" source="nd"/>

<ActionType id="15" source="nd"/>

</Action>

<Reason id="30" source="inferred">In the absence of direct comparisons, the

Update Committee interprets available data as suggesting that benefits of AI therapy represent a “class effect.” Meaningful clinical differences between the commercially available third-generation AIs have not been demonstrated to date.</Reason>

<Reason id="32" source="inferred">Previous results were limited to reports for principal use of a single AI in each of the clinical settings of primary, sequential, or extended adjuvant therapy. There are stillno

data from head-to-head comparisons of AIs. However, there are data from randomized trials for each of the commercially available thirdgeneration AIs for all of the adjuvant treatment strategies (primary,

sequential, and extended). The Update Committee interprets the existing data comparing the AIs with tamoxifen as qualitatively similar with respect to efficacy and tolerability. Toxicity reports have not suggested obvious clinical advantages of one AI over another with respect to compliance, constitutional or menopausal symptoms, bone health, cardiovascular disease, or quality of life. Anecdotal experience suggests that patients may

tolerate one AI better than another, but patterns are neither predictable nor consistent. Two trials—MA.27 and Femara versus Anastrozole Clinical Evaluation (FACE)—are directly comparing one AI

against another as primary adjuvant therapy. However, data are not yet available from either trial.</Reason>

<EvidenceQuality id="21" source="nd">

<EvidenceQualityDescription id="21" source="nd"/>

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<RecommendationStrength id="21" source="nd">

<RecommendationStrengthCode id="21" source="nd"/>

</RecommendationStrength>

<Flexibility id="21" source="nd"/>

<Logic id="21" source="inferred">If &#13;

postmenopausal&#13;&#13;

AND&#13;&#13;

intolerant of one AI&#13;&#13;

AND&#13;&#13;

still candidate for adjuvant endocrine therapy&#13;

Then &#13;

may be advised to consider tamoxifen&#13;&#13;

OR&#13;&#13;

may be advised to consider a different AI</Logic>

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<IntentionalVagueness id="50" source="nd"/>

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</Imperative>

<RecommendationNotes id="7" source="inferred">SCENARIO 4</RecommendationNotes>

</Recommendation>

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<ResearchAgenda id="1" source="nd"/>

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</KnowledgeComponents>

<Testing id="1" source="nd">

<ExternalReview id="1" source="nd"/>

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<ImplementationPlan id="1" source="nd">

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<AnticipatedBarrier id="1" source="nd"/>

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