Proposed New Measure for HEDIS®[1] MY 2020 Osteoporosis Screening in Older Women (OSW)

NCQA seeks comments on a proposed new measure for potential inclusion in the HEDIS 2020 Measurement Year 2020 measure set:

- *Osteoporosis Screening in Older Women:* The percentage of women 65–75 years of age who are screened for osteoporosis.

Osteoporosis is a metabolic bone disorder that affects bone density resulting in higher fracture risk. Without prevention or intervention, osteoporotic fractures can increase the risk of morbidity and mortality. The US Preventive Services Task Force (USPSTF) recommends osteoporosis screening for women 65 and older and for postmenopausal women under 65 who are at increased risk of osteoporosis, as determined by a formal clinical risk assessment tool. The methods of screening cited by the USPSTF include central dual-energy X-ray absorptiometry (DXA), peripheral DXA and quantitative ultrasound (QUS).[2] Male members are not included in the measure, based on the 2018 USPSTF conclusion that there is insufficient evidence to assess the balance of benefits and harms of osteoporosis screening for men.

This new measure replaces *Osteoporosis Testing in Older Women (OTO),* which is being retired from the Medicare Health Outcomes Survey for HEDIS Measurement Year 2020. To ensure that plans have adequate time to screen women after they turn 65, the eligible population includes women at least 67 years old who have been continuously enrolled in a Medicare Advantage plan for two years. Members who are in hospice, with advanced illness and frailty, receiving palliative care, enrolled in an Institutional Special Needs Plan or with a long-term care flag are excluded from the measure, as are members receiving treatment for osteoporosis at any time prior to the measurement year. Treatment is defined as receiving osteoporosis medications, as defined in our value sets.

Focusing the measure on women 65–75 not only improves the measure's validity by narrowing the screening emphasis to the age group with the longest remaining lifespan, it also addresses feasibility and concerns about potential overuse due to limited access to claims data over extended look-back periods for members 75 and older. Excluding members who received treatment further focuses the measure on screening rather than on surveillance of members already under treatment.

Testing revealed that screening for osteoporosis can be feasibly reported at the health plan level, with sufficient denominator size for HEDIS reporting. It showed wide variation in performance across health plans, suggesting a gap in care and room for improvement in providing osteoporosis care. Average plan-level performance indicated that 47.4% of women received one of the USPSTF-approved osteoporosis tests as of age 65; performance ranged from a rate of 34.1% at the 10th percentile of distribution, to 67.3% at the 90th percentile.

We recognize the importance of diagnosis and treatment—as well as assessment of increased osteoporotic risk in women under age 65—as components of good osteoporosis care; we will consider options for capturing these concepts in the future.

Supporting documents for this measure include the draft measure specification and evidence workup.

NCQA acknowledges the contributions of the Geriatric Measurement Advisory Panel and the Osteoporosis Expert Work Group.

[1] HEDIS® is a registered trademark of the National Committee for Quality Assurance (NCQA).
[2] US Preventive Services Task Force (USPSTF). 2018. Final Recommendations Statement: Osteoporosis to Prevent Fractures: Screening. https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/osteoporosis-screening1#consider

Osteoporosis Screening in Older Women (OSW)

SUMMARY OF CHANGES TO HEDIS MEASUREMENT YEAR 2020

- First-year measure.

Description

The percentage of women 65–75 years of age and older who received osteoporosis screening.

Eligible Population

Note: *Members in hospice are excluded from the eligible population. Refer to General Guideline 17: Members in Hospice.*

Product lines Medicare.

Ages 67–75 years as of December 31 of the measurement year.

Continuous enrollment The measurement year and the year prior to the measurement year.

Allowable gap No more than one gap in enrollment of up to 45 days during each year of continuous enrollment.

Anchor date December 31 of the measurement year.

Benefits Medical and Pharmacy.

Required Exclusions Exclude members who meet any of the following criteria:

- Members 67 years of age and older as of December 31 of the measurement year who meet either of the following:
  - Enrolled in an Institutional SNP (I-SNP) any time during the measurement year.
  - Living long-term in an institution any time during the measurement year as identified by the LTI flag in the Monthly Membership Detail Data File. Use the run date of the file to determine if a member had an LTI flag during the measurement year.
- Members 67 years of age and older as of December 31 of the measurement year (all product lines) with frailty ***and*** advanced illness. Members must meet ***BOTH*** of the following frailty and advanced illness criteria to be excluded:
  1. At least one claim/encounter for frailty (Frailty Device Value Set; Frailty Diagnosis Value Set; Frailty Encounter Value Set; Frailty Symptom Value Set) during the measurement year.
  2. Any of the following during the measurement year or the year prior to the measurement year (count services that occur over both years):
     - At least two outpatient visits (Outpatient Value Set), observation visits (Observation Value Set), ED visits (ED Value Set), nonacute inpatient encounters (Nonacute Inpatient Value Set) or nonacute inpatient discharges (instructions below; the diagnosis must be on the discharge claim) on different dates of service, with an advanced illness diagnosis (Advanced Illness Value Set). Visit type need not

be the same for the two visits. To identify a nonacute inpatient discharge:

1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set).
2. Confirm the stay was for nonacute care based on the presence of a nonacute code (Nonacute Inpatient Stay Value Set) on the claim.
3. Identify the discharge date for the stay.

– At least one acute inpatient encounter (Acute Inpatient Value Set) with an advanced illness diagnosis (Advanced Illness Value Set).

– At least one acute inpatient discharge with an advanced illness diagnosis (Advanced Illness Value Set) on the discharge claim. To identify an acute inpatient discharge:

1. Identify all acute and nonacute inpatient stays (Inpatient Stay Value Set).
2. Exclude nonacute inpatient stays (Nonacute Inpatient Stay Value Set).
3. Identify the discharge date for the stay.

– A dispensed dementia medication (Dementia Medications List).

- Members receiving palliative care (Palliative Care Value Set) on at least two different dates of service during the measurement year.
- Members with osteoporosis treatment (Osteoporosis Medication Therapy Value Set; Long-Acting Osteoporosis Medications Value Set; Osteoporosis Medications List) prior to January 1 of the measurement year.

Dementia Medications

Description	Prescription
Cholinesterase inhibitors	• Donepezil • Galantamine • Rivastigmine
Miscellaneous central nervous system agents	• Memantine

Osteoporosis Medications

Description	Prescription	
Bisphosphonates	• Alendronate • Alendronate-cholecalciferol • Ibandronate	• Risedronate • Zoledronic acid
Other agents	• Abaloparatide • Denosumab • Raloxifene	• Romosozumab • Teriparatide

Administrative Specification

Denominator The eligible population.

Numerator Received an osteoporosis screening test (Osteoporosis Screening Tests Value Set) on or between the 65th birthday and December 31 of the measurement year.

Data Elements for Reporting

Organizations that submit HEDIS data to NCQA must provide the following data elements.

Table OSW-3: Data Elements for Osteoporosis Screening in Women

Data Elements	Administrative
Measurement year	✓
Data collection methodology (Administrative)	✓
Eligible population	✓
Number of required exclusions	✓
Numerator events by administrative data	✓
Numerator events by supplemental data	✓
Reported rate	✓

Osteoporosis Screening in Older Women (OSW)
Measure Workup

Topic Overview

Importance and Prevalence

Osteoporosis is the most common metabolic bone disease and is characterized by low bone mineral density and structural deterioration of bone tissue, causing bone fragility and increasing the risk of fractures (National Institutes of Health—The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIH-NIAMS) 2017). It's estimated that approximately 12.3 million people age 50 and older have osteoporosis (Wright 2014). Osteoporosis affects about 25% of women 65 years and older and about 5% of men 65 and older (Looker 2017). Osteoporosis or low bone mass at the femur neck or lumbar spine increases with age. Table 1 illustrates the prevalence of osteoporosis in women and men 50 years of age and older (Looker 2017).

Table 1: Percentage of Adults with Osteoporosis

Age	50-59	60-69	70-79	80+
Women	7%	10%	27%	35%
Men	3%	3%	4%	10%

Researchers applying the National Health and Nutrition Examination Survey (NHANES) data to 2020 and 2030 Census population projections estimated that the population 50 or older with osteoporosis or low bone mass will increase from an estimated 53 million in 2010 to 63.9 million in 2020 and 70.6 million in 2030 (Wright 2014).

Prevalence of the disease varies by race and ethnicity. Non-Hispanic Asians have the highest prevalence of osteoporosis (38.8% women, 6.5% men), followed by Hispanics (17.4% women, 4.2% men) and non-Hispanic Whites (16.0% women, 5.3% men), while non-Hispanic Blacks had the lowest prevalence of osteoporosis (8.0% women, 0% men) (Looker 2017). Despite their lower prevalence of osteoporosis, non-Hispanic Black/African American women face significant disparities in osteoporotic screening and care: They have higher mortality than White women after an osteoporotic hip fracture and are also less likely to be referred for osteoporosis screening than White women of similar risk (Miller et al 2005).

One in two women will experience an osteoporosis-related fracture at some point in their lifetime (US Department of Health and Human Services (USDHHS) 2004). Individuals who experience an osteoporosis-related fracture are also at increased risk of experiencing additional fractures. In one study, women who have had a history of vertebral fracture were four times more likely to experience a new fracture within 15 years, relative to women without a history of vertebral fracture (Cauley 2007).

Osteoporotic fractures, particularly hip fractures, are associated with limited mobility, chronic pain and disability, loss of independence and decreased quality of life (Brauer 2009). Hip and vertebral fractures are the most common osteoporosis-related fractures. Hip fractures are associated with increased disability and mortality: Most hip fractures require surgery, yet 50% of hip fracture patients are unable to walk without assistance after surgery. Nearly 20% of hip fracture patients over age 50 die in the year following their fracture (NIH NIAMS 2017) and 40% of those who survive never return to pre-fracture functional status—often needing long-term nursing home care (USDHHS 2004).

Vertebral fractures can cause chronic back pain and have been linked to increased mortality in older people (NIH NIAMS 2017). The mortality rate for patients with a vertebral fracture is twice that of patients without a vertebral fracture (Lau 2008) and worse overall quality of life—including worse physical function, bodily pain, social function and general health perception (Romagnoli 2004; Salaffi 2007).

Disparities in osteoporosis screening

In a national cohort study, non-Hispanic Asian and Hispanic women 50–79 were most likely to be screened for osteoporosis (Gillespie 2017). Non-Hispanic Black women were least likely to have osteoporosis screening (18.2%) compared with other racial/ethnic categories (Gillespie 2017). In a retrospective cohort study, researchers from the University of California also found that Black women and women with more socioeconomic barriers were less likely to be screened for osteoporosis (Amarnath 2015). Interventions targeting population screening are needed to improve the rates of osteoporosis screening for all women 65 and older, but particularly for Black women and those with lower socioeconomic status.

Financial importance and cost effectiveness

Osteoporosis-related fractures cost patients, their families and the health care system an estimated $19 billion annually (National Osteoporosis Foundation 2018). By 2025, experts predict osteoporosis will be responsible for 3 million fractures, resulting in $25.3 billion in costs (National Osteoporosis Foundation 2018). Between 2000 and 2011, there were 4.9 million hospitalizations for osteoporotic fractures in postmenopausal women in the United States. Osteoporotic fractures account for more than 40% of hospitalizations in this population, compared to myocardial infarction (25%) and stroke (26%) (Singer 2015). The annual total population facility-related hospital cost was highest for hospitalizations due to osteoporotic fractures ($5.1 billion), followed by myocardial infarction ($4.3 billion) and stroke ($3.0 billion) (Singer 2015). In 2002, 50% of the non-fracture, osteoporotic elderly Medicare patients received drug treatment for osteoporosis, averaging $500 per treated patient/year, or $2 billion nationwide (Blume 2011).

Supporting Evidence for Screening

The US Preventive Services Task Force (USPSTF) recommends screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in women 65 years and older (USPSTF 2018). This is a B recommendation, meaning that the USPSTF recommends the service and there is moderate certainty for the net benefit of screening for osteoporosis.

The USPSTF also recommends screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in postmenopausal women younger than 65 who are at increased risk of osteoporosis, as determined by a formal clinical risk assessment tool (USPSTF 2018). One such tool, the FRAX, uses bone density information and other risk factors (e.g., smoking, low BMI, alcohol use, previous fracture) to estimate an individual's 10-year fracture risk. Based on the FRAX tool, a 65-year-old White woman with no other risk factors has a 9.3% 10-year risk for any osteoporotic fracture (USPSTF 2018).

Bone measurement testing

Osteoporosis is characterized by low bone mineral density (BMD) and a resulting increased risk of fractures. The USPSTF found good evidence that BMD measurements accurately predict the risk for fractures in the short-term and that treatments for asymptomatic women with osteoporosis can reduce their risk for fracture. Although there are several advanced screening methods for low BMD, DXA of the hip and lumbar spine ("central DXA") is the most common. DXA quantitatively calculates the photon absorption of the minerals in bone tissue.

Other machine-based tests include peripheral DXA and quantitative ultrasound (QUS). QUS of the calcaneous (heel) is portable and avoids the risk of radiation but does not actually measure BMD and so cannot be used in risk prediction instruments that use BMD. Currently, most diagnostic and treatment criteria for osteoporosis rely on DXA measurements (USPSTF 2018).

Risk assessment tools

Fracture risk assessments have been proposed as alternative strategies to identify individuals who may benefit from treatment. Numerous risk assessment instruments have been developed to either identify low bone density or predict the risk of fracture. These instruments vary in the number and weight assigned to risk factors, but the USPSTF 2018 systematic review found that instruments that assess risk of fracture based on fewer risk factors often had the same (or better) predictive powers as instruments based on more risk factors.

Frequency of screening

The USPSTF did not find clear evidence to inform the optimal intervals for repeated screening and whether repeated screening is necessary in a woman with normal bone mineral density (USPSTF 2018). Limited evidence from two good-quality studies found no benefit in predicting fractures from repeating bone measurement testing 4–8 years after initial screening (Viswanathan 2018). A minimum 2-year gap between testing is needed to reliably measure change in bone mineral density (USPSTF 2018).

Potential harms of screening

The USPSTF did not find evidence that addressed the potential harms of screening for osteoporosis (Viswanathan 2018). The USPSTF evidence review found a single study that assessed harms of screening for osteoporosis, which found no increase in anxiety and no decrease in quality of life from screening (Viswanathan 2018). Harms associated with screening may include radiation exposure from DXA and opportunity costs (time and effort required by patients and the health care system).

Harms of drug therapies for osteoporosis depend on the specific medication used. The USPSTF found that the risk of serious adverse events, upper gastrointestinal events or cardiovascular events associated with the most common class of osteoporosis medication (bisphosphonates) is no greater than small. Overall, the USPSTF found adequate evidence that the harms of osteoporosis medications are small.

Specific Guideline Recommendations

Organization Year	Population	Recommendation	Grade of Recommendation
U.S. Preventive Services Task Force *June 2018*	Women age 65 years and older	The USPSTF recommends screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in women age 65 years and older.	Grade B
	Postmenopausal women younger than age 65 years at increased risk of osteoporosis	The USPSTF recommends screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in postmenopausal women younger than 65 years who are at increased risk of osteoporosis, as determined by a formal clinical risk assessment tool.	Grade B
	Men	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for osteoporosis to prevent osteoporotic fractures in men.	Grade I
American Association of Clinical Endocrinologists (AACE) *September 2016*	All postmenopausal women > 50 years (page 7)	The AACE recommends this population undergo clinical assessment for osteoporosis and fracture risk, including a detailed history and physical examination.	Grade B Level 2
	Women aged 65 and older (page 10)	The AACE recommends bone mineral density testing for women aged 65 and older and younger postmenopausal women at increased risk for bone loss and fracture based on fracture risk analysis.	Grade B Level 2
	Postmenopausal women under the age of 65	The AACE recommends bone mineral density testing for women aged 65 and older and younger postmenopausal women at increased risk for bone loss and fracture based on fracture risk analysis. Risk factors for osteoporosis include prior low-trauma fracture as an adult, advanced age, low bone mineral density, low body weight or blow body mass index, family	Grade C Level 2

Organization Year	Population	Recommendation	Grade of Recommendation
		history of osteoporosis, use of corticosteroids, cigarette smoking, excessive alcohol consumption, and secondary osteoporosis such as rheumatoid arthritis.	

Organization Year	Population	Recommendation
National Osteoporosis Foundation *June 2014*	• Women age 65 and older • Men age 70 and older • Younger postmenopausal women • Women in the menopausal transition • Men age 50-69 with clinical risk factors for fracture • Adults who have a fracture after age 50 • Adults with a condition (rheumatoid arthritis) • Adults taking a medication associated with low bone mass or bone loss	The NOF recommends Bone Mineral Density Testing in these populations.
	• All postmenopausal women • Men age 50 and older	The NOF recommends treating these populations who have had the following outcomes: 1) a hip or vertebral fracture, (2) T-score less than or equal to -2.5 at the femoral neck, total hip or lumbar spine, and (3) low bone mass (T-score between -1.0 and -2.5 at the femoral neck or lumbar spine) and a 10-year probability of a hip fracture greater than or equal to 3% or a 10-year probability of a major osteoporosis-related fracture greater than or equal to 20%.
	Individuals being treated for osteoporosis	The NOF recommends a repeat bone mineral density test every 1-2 years after initiating therapy to reduce fracture risk and every 2 years after that.
North American Menopause Society *2010*	• Women age 65 and over, regardless of clinical risk factors • Postmenopausal women with medical causes of bone loss (e.g. steroid use), regardless of age • Postmenopausal women age 50 and older with additional risk factors • Postmenopausal women with a fragility fracture	The NAMS recommends a bone mineral density test in all these populations.

Organization Year	Population	Recommendation
	All women age 50 and older who have one or more of the following risk factors: fracture after menopause, thinness (body weight <127 or body mass index < 21), history of hip fracture in a parent, current smoker, rheumatoid arthritis diagnoses, and has an alcohol intake of more than two units per day.	The NAMS also recommends that *testing be considered* in this population.
	Women receiving treatment for osteoporosis	NAMS recommends a bone mineral density test after 1-2 years.
	Postmenopausal women *untreated* for osteoporosis	NAMS states that a repeat DXA scan is not useful until 2-5 years have passed.
American Association of Family Physicians, 2011	• Postmenopausal women • Men	Same recommendations as the 2011 USPSTF recommendations (recommended screening for osteoporosis in women age 65 years or older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old White woman who has no additional risk factors, insufficient evidence to assess the balance of benefits and harms of screening in men)
American College of Obstetricians and Gynecologists 2012 (reaffirmed in 2014)	Women	Recommend BMD testing by DXA: • For all women age 65 years or older • For younger women if they are postmenopausal and have other risk factors for fracture and/or a 10-year FRAX risk of fracture ≥9.3% • At intervals not more frequent than every 2 years
American College of Preventive Medicine, 2009	• Women age 65 years or older • Men age 70 years or older	Recommend BMD testing with DXA for all women age 65 years or older and men age 70 years or older, and not more frequently than every 2 years • Younger postmenopausal women and men ages 50 to 69 years should undergo screening if they have at least 1 major or 2 minor risk factors for osteoporosis • Osteoporosis risk assessment tools that estimate absolute fracture risk can be useful supplements to BMD testing, improving the sensitivity and specificity of either approach (BMD or risk assessment) alone; risk assessment can also be used if BMD testing is not readily available or feasible
International Society of Clinical Densitometry, 2015	Men and postmenopausal women	Indications for BMD testing: • Women age 65 years or older • Postmenopausal women younger than age 65 years with risk factors for low bone mass

Organization Year	Population	Recommendation
	All women age 50 and older who have one or more of the following risk factors: fracture after menopause, thinness (body weight <127 or body mass index < 21), history of hip fracture in a parent, current smoker, rheumatoid arthritis diagnoses, and has an alcohol intake of more than two units per day.	The NAMS also recommends that *testing be considered* in this population.
	Women receiving treatment for osteoporosis	NAMS recommends a bone mineral density test after 1-2 years.
	Postmenopausal women *untreated* for osteoporosis	NAMS states that a repeat DXA scan is not useful until 2-5 years have passed.
		• Women during the menopausal transition with clinical risk factors for fracture, such as low body weight, prior fracture, or high-risk medication use • Men age 70 years or older • Men younger than age 70 years with clinical risk factors for low bone mass • Adults with a fragility fracture • Adults with a disease or condition associated with low bone mass or bone loss • Adults taking medications associated with low bone mass or bone loss • Anyone being considered for pharmacologic therapy for osteoporosis • Anyone being treated for osteoporosis to monitor treatment effect • Anyone not receiving therapy in whom evidence of bone loss would lead to treatment • Women discontinuing estrogen should be considered for testing according to the indications listed above
World Health Organization, 2008	Men and women ages 40 to 90 years	DXA and an assessment tool for case-finding high-risk individuals (FRAX) should be used to evaluate fracture risks for men and women. Recommend treatment with FDA-approved medication to lower risk in 3 high-risk groups: • History of fracture of the hip or spine • BMD in the osteoporosis range (T-score ≤-2.5) BMD in the low bone mass or osteopenia range with a higher risk of fracture defined by FRAX score for: • Major osteoporotic fracture 10-year probability ≥20% OR • Hip fracture 10-year probability ≥3%

Grading System Key

U.S. Preventive Services Task Force: What the Grade Means and Suggestions for Practice

Grade	Definition	Suggestion for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	Clinicians may provide this service to selected patients depending on individual circumstances. However, for most individuals without signs or symptoms there is likely to be only a small benefit from this service.	Offer or provide this service only if other considerations support offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of the USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

US Preventive Services Task Force: Levels of Certainty Regarding Net Benefit

- High: The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
- Moderate: The available evidence is insufficient to determine the effects of the preventive services on health outcomes, but confidence in the estimate is constrained by factors such as: (1) the number, size or quality of individual studies, (2) Inconsistency of findings across individual studies, (3) Limited generalizability of findings to routine primary care practice, (4) Lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
- Low: The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: (1) the limited number of size of studies, (2) important flaws in study design and methods, (3) inconsistency of findings across individual studies, (4) gaps in the chain of evidence, (5) findings not generalizable to routine primary care practice, (6) and a lack of information on important health outcomes. More information may allow an estimation of effects on health outcomes.

American Association of Clinical Endocrinologists: Criteria for Grading Recommendation

Grade	Definition
A	Homogenous evidence from multiple well-designed randomized or cohort-controlled trials with sufficient statistical power. ≥1 conclusive level 1 publications demonstrating benefit= risk
B	Evidence from at least 1 large well-designed clinical trial, cohort or case-controlled analytic study, or meta-analysis. No conclusive level 1 publication; ≥1 conclusive level 2 publications demonstrating benefit= risk
C	Evidence based on clinical experience, descriptive studies, or expert consensus opinion. No conclusive level 1 or 2 publications; ≥1 conclusive level 3 publications demonstrating benefit= risk. No conclusive risk at all and no conclusive benefit demonstrated by evidence.
D	Not rated. No conclusive level 1, 2, or 3 publication demonstrating benefit= risk. Conclusive level 1, 2, or 3 publication demonstrating risk= benefit.

2010 American Association of Clinical Endocrinologists Criteria for Rating of Published Evidence*

Numerical Descriptor (Evidence Level)	Semantic Descriptor (reference methods)
1	Meta-analysis of randomized controlled trials
1	Randomized controlled trial
2	Meta-analysis of nonrandomized prospective or case-controlled trials
2	Nonrandomized controlled trial
2	Prospective cohort study
2	Retrospective case-control study
3	Cross-sectional study
3	Surveillance study (registries, surveys, epidemiologic study)
3	Consecutive case series
3	Single case reports
4	No evidence (theory, opinion, consensus, or review)

*1 = strong evidence; 2 = intermediate evidence; 3 = weak evidence; 4 = no evidence.

The American College of Physicians Guideline Grading System

Quality of Evidence	Strength of Recommendation	
	Benefits Clearly Outweigh Risks and Burden or Risks or Burden Clearly Outweigh Risks	Benefits Finely Balanced with Risks and Burden
High	Strong	Weak
Moderate	Strong	Weak
Low	Strong	Weak

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