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DUR DIGEST

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Prevention of Cardiovascular Disease in Women

The American Heart Association has updated their guideline for the Prevention of Cardiovascular Disease in Women. The revision incorporates several new strategies for the prevention of cardiovascular events in women with the key points presented below.

1. T
he guideline stratifies women into three categories (high risk, at risk and ideal cardiovascular health) for assessing cardiovascular risk (Table 1).
2. Women with a 10-year predicted risk for cardiovascular disease of ≥10% are now considered at high risk (as opposed to a 10-year risk for coronary heart disease of ≥20%.
3. Alternatives to the 10-year risk equation are now accepted for the prediction of 10-year global cardiovascular risk such as the Reynolds risk score for women. Previously, the Framingham risk score was only used.
4. Lifestyle interventions include stronger recommendations for increased exercise. Women should be encouraged to accumulate at least 150 minutes of moderate or 75 minutes of vigorous exercise per week (for additional benefit, 300 minutes of moderate or 150 minutes of vigorous exercise per week are recommended), and to sustain aerobic activities for at least 10 minutes per episode. Women should also be encouraged to perform strengthening exercises involving all major muscle groups at least 2 days per week.
5. Diet recommendations are more stringent:
    a. Fruits and vegetables, ≥ 4.5 cups per day
    b. Fish, 2 servings per week (preferably oily types of fish)
    c. Fiber, 30g per day (1.1g fiber per 10g carbohydrate)
    d. Whole grains, 3 servings per day
    e. Sugar, ≤ 5 servings (1 tablespoon) per week
    f. Nuts, legumes, and seeds,, ≥ 4 servings per week
    g. Saturated fat, < 7% of total energy intake
    h. Cholesterol, < 150mg per day
    i. Alcohol ≤ 1 per day
    j. Sodium, < 1500mg (1 teaspoon) per day
    k. Trans-fatty acids, 0
6. Consumption of omega-3 fatty acids in fish or in capsule form may be considered for primary or secondary prevention of cardiovascular events in women with hypercholesterolemia, hypertriglyceridemia, or both.
7. The algorithm for preventative care now includes specific recommendations for stroke prevention in women with atrial fibrillation.
8. There is continued emphasis to avoid therapies without demonstrated benefit or with risks that outweigh their benefits (Class III Interventions):
    a. Noncontraceptive hormone therapy outside of indications for menopausal symptoms
    b. Antioxidant vitamin supplements
    c. Folic acid supplements, except during childbearing years to prevent neural tube defects in offspring
    d. Routine use of aspirin in healthy women aged < 65

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Table 1. Classification of CVD Risk in Women

Risk Status	Criteria
High risk (≥ 1 high-risk states)	Clinically manifest CHD Clinically manifest cerebrovascular disease Clinically manifest peripheral arterial disease Abdominal aortic aneurysm End-stage or chronic kidney disease Diabetes mellitus 10-year Predicted CVD risk ≥ 10%
At risk (≥1 major risk factor[s])	Cigarette Smoking SBP ≥ 120 mm Hg, DBP ≥ 80 mm Hg, or treated hypertension Total cholesterol ≥ 200 mg/dL, HDL-C < 50 mg/dL, or treated dyslipidemia Obesity, particularly central adiposity Poor diet Physical inactivity Family history of premature CVD occurring in first-degree relatives in men < 55 years of age or in women < 65 years of age Metabolic syndrome Evidence of advanced subclinical atherosclerosis (eg, coronary calcification, carotid plaque, or thickened IMT) Poor exercise capacity on treadmill test and/or abnormal heart rate recovery after stopping exercise Systemic autoimmune collagen-vascular disease (eg, lupus or rheumatoid arthritis) History of preeclampsia, gestational diabetes, or Pregnancy-induced hypertension
Ideal cardiovascular health (all of these)	Total cholesterol < 200 mg/dL (untreated) BP <120/<80 mm Hg (untreated) Fasting blood glucose < 100 mg/dL(untreated) Body mass index < 25 kg/m^2 Abstinence from smoking Physical activity at goal for adults > 20 years of age: ≥ 150 min/wk moderate intensity, ≥ 75 min/wk vigorous intensity, or combination Healthy (DASH-like) diet

CVD indicates cardiovascular disease; CHD, coronary heart disease; SPB, systolic blood pressure; DBP, diastolic blood pressure; HDL-C, high-density lipoprotein cholesterol; IMT, intima-media thickness; BP, blood pressure; and DASH, Dietary Approaches to Stop Hypertension.

References:

1. Mosca L et al. Effectiveness-based guidelines for the prevention of cardiovascular disease in women – 2011 update: A guideline from the American Heart Association. *Circulation* 2011 Feb 16. Available at: http://circ.ahajournals.org/cgi/reprint/CIR.0b013e31820faaf8v2?maxtoshow=&hits=10&RESULTFORMAT=&fulltext=effectiveness+based+guidelines+for+the+prevention+of+cardiovascular+disease+in+w&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT. Accessed online February 28, 2011.

FDA Updates and New Drug PA Criteria

FDA Update

- The FDA issued a drug safety communication notifying healthcare professionals and the public that prescription proton pump inhibitors (PPIs) may cause hypomagnesemia if taken for extended periods of time (longer than one year). Low serum magnesium levels can result in serious adverse events including tetany, arrhythmias, and seizures. The FDA recommends obtaining serum magnesium levels prior to starting PPI treatment in patients expected to be on these drugs for long periods of time, as well as patients who take PPIs with medications such as digoxin, diuretics, or drugs that may cause hypomagnesemia. Treatment of hypomagnesemia typically requires magnesium supplements. Treatment in patients taking a PPI and who have hypomagnesemia may also require stopping the PPI. OTC PPIs were not included in this warning since they are marketed at low doses and are only intended for a 14 day course of treatment up to three times per year.
- The FDA is alerting the public of new data that show there is an increased risk for the development of cleft lip and/or cleft palate in infants born to women treated with topiramate during pregnancy. Oral clefts occur in the first trimester of pregnancy before many women know they are pregnant. The benefits and risks of topiramate should be carefully weighed when prescribing this drug for women of child bearing age, particularly when it is considered for a condition not usually associated with permanent injury or death. Alternate medications that have a lower risk of oral clefts and other adverse birth outcomes should be considered for these patients. If topiramate is to be used in women of childbearing age, effective birth control should be used. Because of the new data that show an increased risk of oral clefts, topiramate is being placed in Pregnancy Category D.

New Drug Prior Authorization Criteria

Buprenorphine (Butrans™) Transdermal System: Prior authorization is required for Butrans™. Payment will be considered when the following criteria are met: 1) Previous trials and therapy failures at a therapeutic dose with a preferred long acting morphine sulfate product and methadone. The preferred trials must allow for adequate dose titration and show use of a short acting narcotic for breakthrough pain. 2) A trial and therapy failure with fentanyl patch at maximum tolerated dose. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Extended-Release Alpha$_2$ Agonists: Clonidine (Kapvay™) and Guanfacine (Intuniv®): Prior authorization is required for extended-release alpha$_2$ agonists. Payment will be considered for patient when the following criteria are met: 1) The patient has a diagnosis of ADHD and is between 6 and 17 years of age; and 2) Previous trial with the preferred immediate release product of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance; and 3) Previous trial and therapy failure at a therapeutic dose with one preferred amphetamine and one preferred non-amphetamine stimulant; and 4) Previous trial and therapy failure at a therapeutic dose with atomoxetine (Strattera®). The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Dalfampridine (Ampyra®): Prior authorization is required for dalfampridine (Ampyra®). Payment will be considered under the following conditions: 1) For patients that have a gait disorder associated with MS. 2) Initial authorizations will be approved for 12 weeks with a baseline Timed 25-foot Walk (T25FW) assessment. 3) Additional prior authorizations will be considered at 6 month intervals after assessing the benefit to the patient as measured by a 20% improvement in T25FW from baseline. Renewal will not be approved if the 20% improvement is not maintained. Prior authorizations will not be considered for patients with a seizure diagnosis or in patients with moderate or severe renal impairment.

Medicaid Statistics for Prescription Claims

from October 1, 2010 to December 31, 2010*

Number of claims paid: 1,108,888

Total dollars paid: $64,543,129.65

Percent controlled substances: 18.81%

Average amount paid per claim: $58.22

Average amount paid per claim, brand: $199.52

Average Amount paid per claim, generic: $11.68

Top Drugs by Number of Prescriptions	Top Drugs by Dollars Spent	Top Therapeutic Class by Dollars Spent
ProAir HFA $45.51/RX	*Synagis* 100mg/ml $1,326,399 $2,302.85/RX	Antipsychotics – Atypicals $11.1 million
Hydrocodone/APAP 5-500 $4.71/RX	*Concerta* 36mg $1,277,305 $223.50/RX	Stimulants – Amphetamines – Long Acting $4.4 million
Lexapro 20mg $95.05/RX	*Abilify* 5mg $1,179,375 $439.99/RX	Antidepressants – Selected SSRI's $3.3 million
Cheratussin Syrup AC $5.94/RX	*Adderall* XR 20mg $963,979 $256.26/RX	Anticonvulsants $3.2 million
Tramadol HCL 50mg $5.47/RX	*Abilify 10mg* $960,966 $446.57/RX	Stimulants – Methylphenidate-Long Acting $3.2 million

*All dollars reported are Pre-Rebate