Non-Statin Lipid-Lowering Agents

Statins are the lipid-lowering agents of choice because they have by far the most, and most robust, evidence for reducing cardiovascular events, including death. Non-statins are no longer recommended for routine use. When deciding to start or continue a non-statin, consider the following:

- The addition of a non-statin to a statin has not been proven to further reduce cardiovascular mortality.
- Despite IMPROVE-IT, the FDA denied the expanded indication for morbidity and mortality benefits for ezetimibe.
- Adding a fibrate or niacin to achieve a specific LDL goal could result in reduction of the statin to a suboptimal dose.
- Reinforce statin adherence and lifestyle changes, and check for secondary causes of LDL elevation before adding a non-statin.
- For patients who cannot tolerate the recommended statin dose or who do not achieve the expected statin response (e.g., 50% LDL reduction with high-intensity statin) and are high-risk at baseline, consider adding a non-statin.
  - Consider adding ezetimibe to a statin in high-risk patients, especially those with a recent ACS. There’s no proof that adding other non-statins (fibrates, etc) to a statin improves outcomes, and niacin worsens glycemic control.
  - Consider PCSK9 inhibitors as add-on therapy for HoFH (evolocumab); with maximally tolerated statin for HeFH or clinical CVD requiring additional LDL lowering (evolocumab, alirocumab); and for statin-treated CVD patients with a CV event or multiple risk factors (evolocumab).
  - Consider a bile acid sequestrant, gemfibrozil, or niacin for patients who cannot tolerate a statin.
- Do not add gemfibrozil to a statin due to myopathy risk.
- Consider omega-3 fatty acids, fenofibrate, or niacin if TG ≥500 mg/dL (about 5 mmol/L), or even approaching 1000 mg/dL (about 10 mmol/L). However, there’s no good evidence that lowering triglycerides reduces CV events or prevents pancreatitis.

The chart below provides lipid effects, outcomes, and cost information for the non-statins. (Information in the chart may differ from product labeling). For specifics on lowering triglycerides see our PL Detail-Document, Strategies for Lowering Triglycerides; for more information on the lipid-lowering potential of individual statins in our PL Chart, Characteristics of the Various Statins.

**Abbreviations:** ACS = acute coronary syndrome; CV = cardiovascular; CVD = cardiovascular disease; ER = extended-release; GI = gastrointestinal; HDL = high-density lipoprotein; HeFH = heterozygous familial hypercholesterolemia; HoFH = homozygous familial hypercholesterolemia; IR = immediate release; LDL = low-density lipoprotein; PCSK9 = proprotein convertase subtilisin/kexin type 9; SR = sustained release; SubQ = subcutaneous; TG = triglycerides

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<th>Drug</th>
<th>Lipid Effects&lt;sup&gt;c&lt;/sup&gt;</th>
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| Alirocumab<sup>d</sup> (Praluent) | LDL ↓: 40% to 60%. (Regardless of statin use.) | See Lipid Effects column. | • Post-hoc analysis suggests alirocumab in combination with | • Very expensive.  
• Consider with maximally tolerated statin for HeFH or | U.S.: $1120 (75 mg/two weeks). |
| Continued...  |                           |                                          |                                                        |                                                                          |                                          |

<sup>a</sup> Costs as of July 2015, U.S.
<sup>b</sup> Information in the chart may differ from product labeling.
<sup>c</sup> Lipid Effects: Significant reductions in triglycerides and moderate increases in HDL are often seen. AHAS: atherogenic high density lipoprotein; non-HAP: non-atherogenic high density lipoprotein; non-HLDL: non-high density lipoprotein; FH: familial hypercholesterolemia; RX: prescription; Q: subcutaneous; IM: intramuscular; CAPS: cardiovascular event prevention study; IT: International; HPO: high potency omega-3 fatty acid; EPC: economic and policy consultation; EMF: economic and market franchise; PCSK9: proprotein convertase subtilisin/kexin type 9.

<sup>d</sup> Maximum approved dose for alirocumab is 150 mg every 2 weeks.
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| **Alirocumab, continued**<br>(PCSK9 inhibitor) | | | maximally tolerated statin doses may reduce major CV events in high-risk patients. Further data are needed to confirm [Level B]<sup>55</sup> | clinical CVD requiring additional LDL lowering.<sup>52,67</sup>  
- No adjustment needed with mild to moderate renal or hepatic impairment. No safety data available with severe renal or hepatic impairment.<sup>52,67</sup>  
- Administer via SubQ injection (allow to reach room temperature before injecting).<sup>52,67</sup>  
- No long-term safety data. |  |
| **Bezafibrate**<br>(Bezalip SR, generic bezafibrate SR, generic immediate-release bezafibrate); (Canada only)  
(Fibrac acid) | LDL ↓: 6% to 21% (400 mg).<sup>35,36</sup>  
HDL ↑: 15% to 25% (400 mg).<sup>35,36</sup>  
TG ↓: 25.1% to 42% (400 mg).<sup>35,36</sup> | Further LDL ↓: 1.1% (400 mg).<sup>36</sup>  
Further HDL ↑: 21.6% (400 mg).<sup>36</sup>  
Further TG ↓: 31.7% (400 mg).<sup>36</sup> | • Secondary prevention: prevents composite endpoint of MI and sudden death in a subgroup with TG 200 mg/dL or higher. No increase in non-CV death.<sup>37</sup>  
• First-line option for TG >10 mmol/L.<sup>39</sup>  
• Option for TG 5 to 10 mmol/L.<sup>39</sup>  
• Option for low HDL.<sup>39</sup>  
• Reversible increase in serum creatinine.<sup>33</sup>  
• Requires renal dose adjustment.<sup>33,b</sup>  
• Limited data with statins. | Canada: $75.43 (Bezalip SR) (400 mg/day). |  |
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<td><strong>Cholestyramine</strong>&lt;br&gt;(Questran, Questran Light [U.S.; brands no longer available], Olestyr [Canada])&lt;br&gt;(Bile acid sequestrant)</td>
<td>LDL ↓: 9% (4 g to 8 g/day);&lt;sup&gt;1&lt;/sup&gt; 21% (16 g to 20 g/day);&lt;sup&gt;1&lt;/sup&gt; 23% to 28% (&lt;20 g/day);&lt;sup&gt;1&lt;/sup&gt; HDL ↑: 4% to 8% (16 to 24 g/day);&lt;sup&gt;1&lt;/sup&gt; TG ↑: 11% to 28% (4 g to 24 g/day).&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Further LDL ↓: about 10% (8 g) to about 20% (24 g).&lt;sup&gt;4,5&lt;/sup&gt; Further HDL ↑: 0% to 10%.&lt;sup&gt;3,4&lt;/sup&gt;</td>
<td>• Primary prevention, men: reduces need for bypass, and combined endpoint of coronary heart disease, death, and nonfatal MI (NNT = 59 for 7 years) [Level A]&lt;sup&gt;6,14&lt;/sup&gt; • Secondary prevention, men: with diet, reduces cardiac events vs usual care (not placebo-controlled; events not a primary outcome)[Level B]&lt;sup&gt;7&lt;/sup&gt; Slows progression and increases regression of atherosclerosis.&lt;sup&gt;7,34&lt;/sup&gt;</td>
<td>• Can be difficult to tolerate due to GI side effects such as constipation and gas.&lt;sup&gt;1&lt;/sup&gt;</td>
<td>U.S.: $246.06 (generic packets) (16 g/day). Canada: $203.04 (Olestyr) (16 g/day).</td>
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<td><strong>Colestevlam</strong>&lt;br&gt;(WelChol [U.S.], Lodalis [Canada])&lt;br&gt;(Bile acid sequestrant)&lt;br&gt;(FDA-approved for glycemic control in type 2 diabetes)&lt;sup&gt;2&lt;/sup&gt;</td>
<td>LDL ↓: 15% to 19.1% (3.8 g/day).&lt;sup&gt;2,8&lt;/sup&gt; HDL ↑: 3% to 8.1% (3.8 g/day).&lt;sup&gt;2,8&lt;/sup&gt; TG ↑: 10% (3.8 g/day; about 20% when used with insulin or sulfonylureas).&lt;sup&gt;2&lt;/sup&gt;</td>
<td>Further LDL ↓: 10% to 16% (3.8 g/day).&lt;sup&gt;2&lt;/sup&gt; Further HDL ↑: 3% to 7% (3.8 g/day).&lt;sup&gt;2&lt;/sup&gt;</td>
<td>• None.</td>
<td>• Limited data with statins. • Studied in combination with atorvastatin, lovastatin, pravastatin, and simvastatin.&lt;sup&gt;2,10&lt;/sup&gt; • Potential lower risk of GI side effects compared to cholestyramine and colestipol.&lt;sup&gt;8,64&lt;/sup&gt;</td>
<td>U.S.: $565.20 (3.8 g/day). Canada: $216.84 (3.8 g/day).</td>
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<td><strong>Colestipol</strong></td>
<td><strong>LDL ↓: 5% (2 g/day) to 26% (16 g/day).</strong>$^1$</td>
<td>Further LDL ↓: 10% (5 g/day) to 12% (10 g/day).$^{11}$</td>
<td>- Reduces progression of atherosclerosis and events when combined with niacin or lovastatin (events not a primary outcome).$^{50}$</td>
<td>- Can be difficult to tolerate due to GI side effects such as constipation and gas.$^8$</td>
<td>U.S.: $188.66 (generic) (10 g/day). Canada: $71.52 (10 g/day).</td>
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<td>(Colestid, generic [U.S.])</td>
<td>(Bile acid sequestrant)</td>
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<td><strong>Evolocumab</strong></td>
<td><strong>LDL ↓: 42% to 65%.</strong>$^{58,59,61,63}$ (Regardless of statin use.)</td>
<td>See Lipid Effects column.</td>
<td>- Lowered LDL 34% to 38.5% more compared to ezetimibe.$^{58,60}$</td>
<td>- Very expensive. Consider as add-on therapy for HoFH; with maximally tolerated statin for HeFH or clinical CVD requiring additional LDL lowering; and for statin-treated CVD patients with a CV event or multiple risk factors.$^{53,54,61}$</td>
<td>U.S.: $1054.62 (140 mg every two weeks). Canada: $603.42 (140 mg every two weeks).</td>
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<td>(Repatha)</td>
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<td>- Added to a high- or moderate-dose statin, prevents one CV death, MI, or stroke for every 74 high-risk CVID patients treated for about two years (FOURIER study). CV death as a stand-alone outcome not affected. Most patients had a prior MI, and about one third had diabetes and/or smoked.$^{61}$</td>
<td>- Administer by SubQ injection (allow to reach room temperature before injecting).$^{53,54}$</td>
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<td>(PCSK9 inhibitor)</td>
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<td>- No dosage adjustment needed with mild to moderate renal or hepatic impairment. No safety data available for patients</td>
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<td>Evolocumab, continued</td>
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<td>with severe renal or hepatic impairment&lt;sup&gt;53,54&lt;/sup&gt;</td>
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<td>Ezetimibe (Zetia [U.S.], Ezetrol, generics [Canada]) (Cholesterol absorption inhibitor) (In U.S., available in combination with simvastatin [Vytorin] and atorvastatin [Liptruzet]).</td>
<td>LDL ↓: 18% (10 mg/day)&lt;sup&gt;12,13&lt;/sup&gt;</td>
<td>Further LDL ↓: 25%.&lt;sup&gt;13&lt;/sup&gt;</td>
<td>With simvastatin 20 mg, reduces first major atherosclerotic event in chronic renal disease [Level A].&lt;sup&gt;29&lt;/sup&gt;</td>
<td>Consider ezetimibe as a moderate-dose statin add-on for high-risk secondary prevention patients who can’t tolerate a high-intensity statin, or who don’t get the expected 50% LDL reduction with a high-intensity statin.&lt;sup&gt;49&lt;/sup&gt;</td>
<td>U.S.: $259.96 (10 mg/day). Canada: $50.81 (generic) (10 mg/day). (Vytorin [U.S.]: $257.58 [10 mg/20 mg/day]). (Liptruzet [U.S.]: $165.00 [10mg/20mg/day]).</td>
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<td>Fenofibrate (Tricor, Lofibra, Trilipix, Antara [U.S.], Lipidil EZ [Canada], others, generics) (Fibric acid) Continued...</td>
<td>LDL ↓: 20.6% (145 mg)&lt;sup&gt;15&lt;/sup&gt;</td>
<td>Further LDL ↓: 0% to 6% (200 mg)&lt;sup&gt;16-18&lt;/sup&gt;</td>
<td>Prevention of CV events in type 2 diabetes: did not reduce primary composite outcome (non-fatal MI or CV death). Improved outcomes included non-fatal MI (24%↓), coronary revascularization</td>
<td>First-line option for TG &gt;10 mmol/L&lt;sup&gt;39&lt;/sup&gt; (about 1000 mg/dL). Option for TG &gt;500 mg/dL&lt;sup&gt;38&lt;/sup&gt; or 5 to 10 mmol/L&lt;sup&gt;39&lt;/sup&gt; Option for low HDL&lt;sup&gt;39&lt;/sup&gt; Requires renal dose adjustment.&lt;sup&gt;33,b&lt;/sup&gt; Associated with</td>
<td>U.S.: $27.92 (generic) (48 mg/day). U.S.: $15.29 (generic) (145 mg/day). Canada: $29.53 (generic) (145 mg/day).</td>
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<td><strong>Fenofibrate</strong>, continued</td>
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<td>(21%), progression to albuminuria, and reduced laser treatments for retinopathy. Non-significant increase in CV death.&lt;sup&gt;31&lt;/sup&gt;</td>
<td>reversible increase in serum creatinine.&lt;sup&gt;33&lt;/sup&gt; • Unclear risk of cholelithiasis.&lt;sup&gt;51&lt;/sup&gt; • In the U.S., FDA indication for fenofibric acid (<em>Trilipix</em>) use with statins revoked in April 2016 due to lack of CV benefit.&lt;sup&gt;57&lt;/sup&gt; • Fenofibrate is still indicated as monotherapy for lipid lowering.&lt;sup&gt;66&lt;/sup&gt; • Preferred over gemfibrozil for use with statins for safety.&lt;sup&gt;33&lt;/sup&gt;</td>
<td>Canada: $8.82 (generic) (200 mg/day).</td>
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<td><strong>Gemfibrozil</strong>&lt;br&gt;(<em>Lupid</em> [U.S.], generics)&lt;br&gt;(<em>Fibric acid</em>)</td>
<td>LDL: No effect.&lt;sup&gt;21&lt;/sup&gt; HDL ↑: 6% (1200 mg/day).&lt;sup&gt;21&lt;/sup&gt; TG ↓: 33% to 50% (greatest drop in patients with highest triglycerides) (1200 mg/day).&lt;sup&gt;21,41&lt;/sup&gt;</td>
<td>Further TG ↓: 41%.&lt;sup&gt;19&lt;/sup&gt; Further HDL ↑: 9%.&lt;sup&gt;19&lt;/sup&gt;</td>
<td>• Primary prevention, men: reduced sudden cardiac death plus fatal/nonfatal MI (NNT = 71 over 5 years)[Level A].&lt;sup&gt;20&lt;/sup&gt; • Secondary prevention of nonfatal MI plus cardiac death in men with low HDL</td>
<td>• First-line option for TG &gt;10 mmol/L.&lt;sup&gt;39&lt;/sup&gt; (about 1000 mg/dL). • Option for TG ≥500 mg/dL&lt;sup&gt;38&lt;/sup&gt; or 5 to 10 mmol/L.&lt;sup&gt;39&lt;/sup&gt; • Option for low HDL.&lt;sup&gt;39&lt;/sup&gt; • Requires renal dose adjustment.&lt;sup&gt;33,b&lt;/sup&gt; • Avoid with statin.&lt;sup&gt;33,39&lt;/sup&gt; • No mortality benefit.&lt;sup&gt;20,21&lt;/sup&gt;</td>
<td>U.S.: $6.85 (generic) (1200 mg/day). Canada: $33.42 (generic) (1200 mg/day).</td>
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<td><strong>Gemfibrozil, continued</strong></td>
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<td>(NNT = 23 over 5 years)[Level A]&lt;sup&gt;21&lt;/sup&gt;</td>
<td>• Unclear risk of cholelithiasis&lt;sup&gt;51&lt;/sup&gt;</td>
<td>U.S.: $234.48 (4 g/day).</td>
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<td><strong>Icosapent ethyl</strong></td>
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<td>• Option for TG ≥500 mg/dL&lt;sup&gt;46&lt;/sup&gt;</td>
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<td>(Vascepa) (U.S. only)</td>
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<td>• Safe for use with statin&lt;sup&gt;47&lt;/sup&gt;</td>
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<td>(EPA; about 1 g omega-3s/capsule)</td>
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<td></td>
<td>• Use caution with fish or shellfish allergy&lt;sup&gt;46&lt;/sup&gt;</td>
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<td><strong>Niacin</strong></td>
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<td>U.S.: $19.48 (Niacor 1 g/day).</td>
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<td>(Niacor [IR; U.S. only], Niaspan [ER],</td>
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<td>U.S.: $274.22 (Niaspan 1 g/day).</td>
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<td>Niaspan FCT [Canada])</td>
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<td>Canada: $39.57 (Niaspan 1 g/day).</td>
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<td>In the U.S., niacin was available as a</td>
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<td>Canada: $43.53 (Niaspan FCT 1 g/day).</td>
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<td>combo with lovastatin (Advicor) and</td>
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<td>simvastatin (Simcor). Both products</td>
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<td>voluntarily withdrawn from the market in</td>
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<td>December 2015.&lt;sup&gt;62&lt;/sup&gt;</td>
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<td>Niacin, continued</td>
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<td>controlled LDL, low HDL, and high TG.</td>
<td>monotherapy for dyslipidemia.</td>
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<td>In the U.S., niacin IR and ER are approved for monotherapy or for use with bile acid sequestrants.</td>
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<td>Omega-3 ethyl esters (Lovaza) (EPA/DHA; about 1 g omega-3s/capsule).</td>
<td>LDL ↑: 44.5% (4 g/day).&lt;sup&gt;27&lt;/sup&gt;</td>
<td>LDL ↑: 0.7% (4 g/day).&lt;sup&gt;27&lt;/sup&gt;</td>
<td>Secondary prevention: reduces cardiovascular death, sudden death, and combined endpoint of death, non-fatal MI, and non-fatal stroke [Level B].&lt;sup&gt;26&lt;/sup&gt;</td>
<td>Option for TG ≥500 mg/dL (about 5 mmol/L).&lt;sup&gt;38&lt;/sup&gt;</td>
<td>U.S.: $290.63 (4 g/day).</td>
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<td>HDL ↑: 9.1% (4 g/day).&lt;sup&gt;27&lt;/sup&gt;</td>
<td>Further HDL ↑: 3.4% (4 g/day).&lt;sup&gt;27&lt;/sup&gt;</td>
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<td>Safe for use with statin.</td>
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<td>TG ↓: 45% (4 g/day).&lt;sup&gt;27&lt;/sup&gt;</td>
<td>Further TG ↓: 29.5% (4 g/day).&lt;sup&gt;27&lt;/sup&gt;</td>
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<td>Associated with an increase in risk for recurrence of symptomatic atrial fibrillation or flutter within first three months of therapy.&lt;sup&gt;27&lt;/sup&gt;</td>
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<sup>a</sup> U.S. cost is wholesale acquisition cost (WAC)
<sup>b</sup> Maximum daily dose if CrCl <60 mL/min: bezafibrate 200 mg, gemfibrozil 600 mg, and fenofibrate 67 mg. Avoid if CrCl <15 mL/min.<sup>33</sup>
<sup>c</sup> TG-lowering effects of niacin, omega-3-ethyl esters, and fibrates is greatest in patients with higher baseline TG levels.<sup>33</sup>-<sup>45</sup>
<sup>d</sup> Lipid levels off statin therapy may be required for prior authorization.
Levels of Evidence

In accordance with the trend towards Evidence-Based Medicine, we are citing the LEVEL OF EVIDENCE for the statements we publish.

<table>
<thead>
<tr>
<th>Level</th>
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| A     | High-quality randomized controlled trial (RCT)  
High-quality meta-analysis (quantitative systematic review) |
| B     | Nonrandomized clinical trial  
Nonquantitative systematic review  
Lower quality RCT  
Clinical cohort study  
Case-control study  
Historical control  
Epidemiologic study |
| C     | Consensus  
Expert opinion |
| D     | Anecdotal evidence  
In vitro or animal study |


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References


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