Reviewer No. 1 check list for application for addition:
Antipsychotics and Antidepressants PART 1:
ANTIPSYCHOTICS

(1) Have all important studies that you are aware of been included?

Yes   No   X

If "No", add missing references with brief summary of key findings.

Relevant Cochrane reviews, as well as more recent overviews from the Drug Effectiveness Review Project have not been cited:

McDonagh MS, Peterson K, Carson S, Chan B, Thakurta S. Drug class review on atypical antipsychotic drugs. Update #2 final report. updated 2008
http://www.ohsu.edu/drugeffectiveness/reports-final.cfm


There are Cochrane protocols for aripiprazole, clozapine, quetiapine, and olanzapine vs other atypical antipsychotics.
(2) **Is there adequate evidence of efficacy for the proposed use?**

Yes X but not to differentiate among atypical antipsychotics No □

If "No", suggest what is needed.

There is adequate evidence from randomized controlled trials and systematic reviews regarding the efficacy and safety of the proposed drugs compared to placebo or older antipsychotics (particularly haloperidol). Approximately 70 head to head trials of various combinations of the atypical antipsychotics have been reviewed. A variety of outcomes have been assessed in these trials. Good quality trial evidence does not indicate differences in quality of life measures among these drugs. There are no consistent differences in short-term efficacy trials. Good quality trial evidence indicates lower rates of hospitalization and lower drug discontinuation rates with olanzapine compared to quetiapine, risperidone, ziprasidone and aripiprazole.

(3) **Is there evidence of efficacy in diverse settings and/or populations?**

Yes x No □

If "No", suggest what is needed.

The majority of trials of clozapine are in treatment resistant populations.

(4) **Are there adverse effects of concern?**

Yes X No

If "Yes", (list / describe)

Among the atypical antipsychotics, rates of patients experiencing extrapyramidal side effects were similar. Olanzapine and clozapine are associated with greater increases in triglycerides and weight gain compared to risperidone.

(5) **Are there special requirements or training needed for safe/effective use?**

Yes X No

If "Yes", describe.

Clozapine requires blood level monitoring for aggranulocytosis during early treatment.

(6) **Is this product needed to meet the majority health needs of the population?**

Yes X No □

If "No", is there a special reason why this should be on the Model List?

(7) **Is the proposed dosage form registered by a stringent regulatory authority?**

Yes X No □

If "No", give details.
(8) **What action do you propose for the Committee to take?**
The addition of an atypical antipsychotic is supported by the evidence. Recommend that risperidone be added to the list. The proposed drugs have comparable efficacy and risperidone has a favourable adverse event and cost profile.

Consider adding clozapine to the complementary list for treatment resistant patients with monitoring required.

(9) **Additional comment, if any.**

… I believe that risperidone will soon be off patent…………
Reviewer 1 check list for application for addition:
PART 2: ANTIDEPRESSANTS

Note: the application recommends the addition of fluoxetine, paroxetine and sertraline, but fluoxetine is on the list (24.2.1), so paroxetine and sertraline are considered for this review.

(1) **Have all important studies that you are aware of been included?**

Yes   No   X

If "No", add missing references with brief summary of key findings.

Relevant Cochrane reviews, as well as more recent overviews from the Drug Effectiveness Review Project have not been cited:


(2) **Is there adequate evidence of efficacy for the proposed use?**

Yes   No   X

If "No", suggest what is needed.

A meta-analysis of 5 randomized controlled trial comparing fluoxetine to sertraline slightly favoured sertraline (RR 1.1 (1.01,1.20); ARR 0.062 (0.007,0.115), but found no statistically significant differences between fluoxetine and paroxetine (Gartlehner et al).

(3) **Is there evidence of efficacy in diverse settings and/or populations?**

Yes   X   No

If "No", suggest what is needed.

(4) **Are there adverse effects of concern?**

Yes   X   No

If "Yes", (list / describe)

No significant differences between fluoxetine, sertraline and paroxetine.
(5) Are there special requirements or training needed for safe/effective use?

Yes ☐ No X

If "Yes", describe.

(6) Is this product needed to meet the majority health needs of the population?

Yes X No ☐

If "No", is there a special reason why this should be on the Model List?

(7) Is the proposed dosage form registered by a stringent regulatory authority?

Yes X No ☐

If "No", give details.

(8) What action do you propose for the Committee to take?

Do not add sertraline and paroxetine to the list. Fluoxetine remains on list.

(9) Additional comment, if any.