

*New York Department of Health  
Evidence-based Review Process  
for Coverage Determinations*

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**Dossier Submission Form**

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# Submission Checklist

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The following information should be included in the dossier submission:

- ✓ **Overview, Contact Information, PICO and Executive Summary**
- ✓ **Service Rationale**
- ✓ **References & Quality Appraisal Ratings**
  - **Full PDF copies of all references and articles cited**
  - **Completed Quality Appraisal Checklist for each study submitted**
- ✓ **Overall Strength of Body of Evidence**
- ✓ **Net Impact Worksheet**
- ✓ **Supporting Documents (e.g., FDA approval letter, IRB protocol, trial registration – *if applicable*)**

All forms should be completed in 12 pt Calibri font with one-inch margins. **Please do not exceed 6,000 words on the Service Rationale** (excluding PDF copies of references). Failure to follow these submission requirements will result in the entire dossier submission not being reviewed. Please submit six hard copies and four electronic copies (USB devices) of your dossier submission to:

New York State Department of Health  
Office of Health Insurance Programs  
99 Washington Ave.  
One Commerce Plaza - 720  
Albany, NY 12210  
ATTN: Dossier Review Unit

# Overview and Contact Information

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## Contact Information

Name of Individual Submitting Dossier	
Company/Organization	
Address	
Phone	
Email address	

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## Technology Information

Service Under Review	
Manufacturer(s)	
Description of Service	

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## Applicable Codes

What HCPCS or CPT® codes can be used to bill for this service? <i>Please list all applicable codes.</i>	
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## PICO

The Population, Intervention, Comparator, and Outcome framework, otherwise known as the PICO, helps to define the literature search parameters and forms the basis of establishing specific research questions on a topic. For services with wide applicability, the PICO can assist in focusing the evidence review to a manageable research topic. An example topic submission is available in Appendix A.

**Table 1. PICO Submission**

<b>Population(s)</b>		
<b>Intervention(s)</b>		
<b>Comparator(s)</b>		
<b>Outcomes</b> (please list <u>up to five</u> outcomes to be considered in this review)	Outcome (e.g., cardiac events)	
	1.	
	2.	
	3.	
	4.	
	5.	
	<b>Harms</b> (please list <u>all</u> patient important harms associated with this product, provide a timeframe for each harm, and list in order of severity and patient importance (e.g., mortality should be listed first if applicable))	1.
		2.
		3.
		4.
5.		
<i>(add lines as needed)</i>		

Please affirm that the dossier submission is complete and accurate and includes all available relevant data.

\_\_\_\_\_  
Signature of Dossier Submitter

\_\_\_\_\_  
Date

# Executive Summary

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Please provide an overview of the service in the space provided below (250 to 750 words). The summary should include a short description of the service, included evidence, and all related harms. The executive summary may be used on the Department's website and should be written at a reading level for general public consumption.

# Service Rationale

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The following questions inquire about the safety and efficacy of the service under review and its applicability to the New York Medicaid population. The use of the term “service” refers to medical or surgical treatment procedures, devices, and diagnostics. Please cite your responses and list all references in the *References & Quality Appraisal Ratings* section. Please answer the questions below using 12 pt Calibri font with one inch margins. DO NOT EXCEED 6,000 WORDS TOTAL IN ANSWERING THE QUESTIONS BELOW.

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**1. The service must have final approval from the appropriate US governmental regulatory bodies (e.g., FDA), if applicable.**

- a) What is/are the licensed use(s) of this service?
- b) Does the service have FDA or other regulatory agency approval and for what use(s)?  
What approval process was employed (e.g., 510(k), Premarket Approval, Investigational Device Exemption)?
- c) Please submit approval letter from the FDA or other regulatory agency, if applicable.

**2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.**

- a) Please specify how the submitted references demonstrate the efficacy and/or effectiveness of this service.
- b) Please disclose all potential harms or other safety concerns regarding this service (e.g., side effects, adverse effects).

**3. The service must improve the net health outcome of a population.**

- a) How would this service increase the health of New York State Medicaid patients?

**4. The service must be at least as beneficial as any established alternatives.**

- a) How is this service (1) different from, and (2) more effective than services that currently address the medical conditions for which this service is intended for use?
- b) How does the safety of this service compare with other services that are currently used to treat the medical conditions in question?
- c) If this is a diagnostic service, what is the current best diagnostic strategy (i.e., diagnostic gold standard), and how does this service compare with it?

**5. The improvement must be attainable outside of the investigational settings.**

- a) Please specify which submitted references discuss the clinical effectiveness of the service and its effect on health outcomes outside the investigational setting (e.g., in general community medical practice, among populations with known co-morbidities).

**6. The service must be cost-effective or cost neutral outside the investigational setting.**

- a) What is the total cost for the service (e.g., costs of related physician services or outpatient hospital charges or other services that patients using the service will need)? Please include both initial costs and estimated lifetime costs.
- b) Please compare the total cost of the service with the cost of established services that currently address the medical conditions for which this service is intended for use? Please include both initial costs and estimated lifetime costs.

**7. Other payer coverage of the service.**

- a) Which State Workers' compensation programs and private Health Plans nationwide cover the use of this service, and have there been any Centers for Medicare or Medicaid Services national or local coverage determinations?
- b) Are there any restrictions of this coverage? If yes, please list.

# References & Quality Appraisal Ratings

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Please provide an alphabetical list (by last name of first author) of all references included in the dossier submission and the respective methodological quality appraisal ratings for each study. Every study must be assessed using the respective Quality Appraisal Checklists (provided below). See the *Dossier Methods Guidance* document for further information on appraising studies for methodological quality.

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Reference	Study Design <sup>1</sup>	Methodological Quality Appraisal Rating (Good, Fair, Poor)
<i>Example: Smith, A.E., Gardner, E.F., &amp; Hoh, D. (2012). Efficacy of magnetic resonance imaging for breast cancer screening. Annals of Internal Medicine, 3(12), 345-349.</i>	RCT	Fair

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<sup>1</sup>Please list study design (e.g., systematic review, meta-analysis, technology assessment, randomized controlled trial, cohort, case-control, cross-sectional, case series, economic study). See *Dossier Methods Guidance* for more information on study designs.

# Overall Strength of Body of Evidence

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Based on the methodological quality appraisal rating for each reference, please provide the overall strength of the evidence for each outcome and harm as specified by the topic description. See the *Dossier Methods Guidance* document for further information on assessing the overall strength of a body of evidence.

The overall strength of the body of evidence for each outcome and harm should be graded as: **High, Moderate, Low, or Very Low**. Where there is no evidence for an outcome, please list as “None.”

*NOTE: Please complete this section after completing the individual Quality Appraisal Checklist(s) for each study.*

	<b>Overall Strength of Body of Evidence</b> <i>(e.g., High, Moderate, Low, Very Low)</i>	<b>Rating Rationale</b> <i>(Please discuss study design and quality. Note any inconsistencies, indirectness, imprecision, and publication bias in results.)</i>
<b>Outcome #1:</b>		
<b>Outcome #2:</b>		
<b>Outcome #3:</b>		
<i>[Add as many rows as necessary]</i>		

	<b>Overall Strength of Body of Evidence</b> <i>(e.g., High, Moderate, Low, Very Low)</i>	<b>Rating Rationale</b> <i>(Please discuss study design and quality. Note any inconsistencies, indirectness, imprecision, and publication bias in results.)</i>
<b>Harm #1:</b>		
<b>Harm #2:</b>		
<b>Harm #3:</b>		
<i>[Add as many rows as necessary]</i>		

# Net Impact Worksheet

There are a number of ways to quantify the effect of a service on health outcomes. Such effects include both harms and benefits, and both must be taken into account to determine the net impact of a service. Measures of effectiveness include such calculations as odds ratio, relative risk, effect size, and number needed to treat. Diagnostic efficacy is measured using sensitivity, specificity, positive and negative predictive values and likelihood ratios. Measures of harm include such calculations as hazard ratio and number needed to harm. The calculations reported in this section will vary depending on what outcomes are being measured. For diagnostic services, please provide all appropriate calculations, as demonstrated in the example tables below. Please provide similar information for therapeutic services, as demonstrated in the second example table below.

## **Diagnostic Example: MRI for Breast Cancer Screening**

### OUTCOME #1: Detection of Breast Cancer

Citation (Author, Year)	Baseline prevalence in population being tested	Time frame	Statistical Measure	Result
<b>WA HTA, 2006</b>	<i>High risk (&gt; 20% lifetime risk of breast cancer)</i>	<i>Per screening</i>	<i>Sensitivity</i>	<i>64-100%</i>
	<i>High risk (&gt; 20% lifetime risk of breast cancer)</i>	<i>Per screening</i>	<i>Specificity</i>	<i>75-100%</i>
	<i>High risk (&gt; 20% lifetime risk of breast cancer)</i>	<i>Per 100 screenings</i>	<i>Number of additional breast cancers detected (over mammographic screening only)</i>	<i>2-5</i>
<b>Sardanelli, 2004</b>	<i>All participants were planning mastectomy</i>	<i>Per screening</i>	<i>PPV</i>	<i>68% vs 76% for mammography</i>

Citation (Author, Year)	Baseline prevalence in population being tested	Time frame	Statistical Measure	Result
<i>Warner, 2008</i>	<i>High risk (&gt; 20% lifetime risk of breast cancer)</i>	<i>Per screening</i>	<i>+Likelihood Ratio</i>	<i>4.2 (3.0 to 5.9) vs 8.7 (4.4 to 17.5) for mammography</i>

**OUTCOME #2:** Additional procedures as a consequence of false positive results

Citation (Author, Year)	Baseline prevalence in population being tested	Time frame	Statistical Measure	Result
<i>WA HTA, 2006</i>	<i>High risk (&gt; 20% lifetime risk of breast cancer)</i>	<i>Per 100 screenings</i>	<i>Number of additional benign biopsies (over mammographic screening only)</i>	<i>11</i>

**Harm #1:** Mortality

Citation (Author, Year)	Baseline prevalence in population being tested	Time frame	Statistical Measure	Result
<i>WA HTA, 2006</i>			<i>No evidence</i>	<i>---</i>

**Therapeutic Example: Repetitive Transcranial Magnetic Stimulation (rTMS) for Treatment Resistant Depression**

**OUTCOME #1: Improvement in Depression Symptoms**

Citation (Author, Year)	Treatment Group Rate # pts w/outcome in group total # of pts in group	Control Group Rate # pts w/outcome in group total # of pts in group	Time Frame	Statistical Measure	Result
AHRQ, 2012	NA	NA	Variable – meta-analysis	Difference in change in HamD score	-5.74 (95% CI - 7.79 to -3.68)

**OUTCOME #2: Treatment Response**

Citation (Author, Year)	Treatment Group Rate # pts w/outcome in group total # of pts in group	Control Group Rate # pts w/outcome in group total # of pts in group	Time Frame	Statistical Measure	Result
AHRQ, 2012	NR	NR	Variable – meta-analysis	Relative Risk	3.34 (95% CI 1.92 to 5.82)
Avery et al., 2006	11/35 = 0.2	2/33 = 0.0303	5 weeks	NNT	6

**OUTCOME #3: Remission**

Citation (Author, Year)	Treatment Group Rate # pts w/outcome in group total # of pts in group	Control Group Rate # pts w/outcome in group total # of pts in group	Time Frame	Statistical Measure	Result
AHRQ, 2012	NR	NR	Variable – meta-analysis	Relative Risk	6.12 (95% CI 1.89 to 19.80)

Citation (Author, Year)	Treatment Group Rate <u># pts w/outcome in group</u> total # of pts in group	Control Group Rate <u># pts w/outcome in group</u> total # of pts in group	Time Frame	Statistical Measure	Result
<i>Avery et al., 2006</i>	7/35 = 0.2	1/33 = 0.0303	5 weeks	NNT	5

**HARM #1:** Specific Adverse Effects

Citation (Author, Year)	Treatment Group Rate <u># pts w/outcome in group</u> total # of pts in group	Control Group Rate <u># pts w/outcome in group</u> total # of pts in group	Time Frame	Statistical Measure	Result
<i>Avery et al., 2006</i>	14/35 = 0.4	0/33 = 0	5 weeks	Scalp Pain NNH	3

NA = Not applicable

NR = Not reported

**Diagnostic Tables**

*Please fill out a table for each outcome, as specified on the service review webpage.*

OUTCOME #1: \_\_\_\_\_

Citation (Author, Year)	Baseline prevalence in population being tested	Time frame	Statistical Measure	Result

*Please fill out a table for each harm, as specified on the service review webpage.*

HARM #1: \_\_\_\_\_

Citation (Author, Year)	Baseline prevalence in population being tested	Time frame	Statistical Measure	Result

**Therapeutic Tables**

Please fill out a table for each outcome, as specified on the service review webpage.

OUTCOME #1: \_\_\_\_\_

Citation (Author, Year)	Treatment Group Rate <u># pts w/outcome in group</u> total # of pts in group	Control Group Rate <u># pts w/outcome in group</u> total # of pts in group	Time Frame	Statistical Measure	Result

Please fill out a table for each harm, as specified on the service review webpage.

HARM #1: \_\_\_\_\_

Citation (Author, Year)	Treatment Group Rate <u># pts w/outcome in group</u> total # of pts in group	Control Group Rate <u># pts w/outcome in group</u> total # of pts in group	Time Frame	Statistical Measure	Result

# Quality Appraisal Checklists

<b>NEW YORK DEPARTMENT OF HEALTH</b>		<b>Quality Appraisal Checklist: Systematic Reviews and Meta-analyses</b>			
Study citation ( <i>Include last name of first author, title, year of publication, journal title, pages</i> )					
Technology:					
Checklist completed by:					Date:
<b>SECTION 1: INTERNAL VALIDITY</b>					
<i>In a well conducted systematic review</i>			<i>In this study the criterion is met:</i>		
1.1	The study addresses an appropriate and clearly focused question.	YES	NO	UNCLEAR	N/A
1.2	An adequate description of the methodology used is included, and the methods used are appropriate to the question.	YES	NO	UNCLEAR	N/A
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	YES	NO	UNCLEAR	N/A
1.4	The criteria used to select articles for inclusion is appropriate.	YES	NO	UNCLEAR	N/A
1.5	Study quality is assessed and taken into account.	YES	NO	UNCLEAR	N/A
1.6	There are enough similarities between the studies selected to make combining them reasonable.	YES	NO	UNCLEAR	N/A
1.7	Competing interests of members have been recorded and addressed.	YES	NO	UNCLEAR	N/A
1.8	Views of funding body have not influenced the content of the study.	YES	NO	UNCLEAR	N/A
<b>SECTION 2: OVERALL APPRAISAL OF THE STUDY</b>					
2.1	How well was the study done to minimize bias? <i>Code: Good, Fair or Poor</i>	GOOD	FAIR	POOR	

2.2	If coded as fair or poor, what is the likely direction in which bias might affect the study results?				
2.3	Are the results of this study directly applicable to the patient group targeted by this key question?	YES	NO	UNCLEAR	N/A
2.4	Other reviewer comments:				

Center for Evidence-based Policy 2009. Adapted from NICE and SIGN materials.

NEW YORK DEPARTMENT OF HEALTH		Quality Appraisal Checklist: Randomized Controlled Trials			
Study identification (Include author, title, year of publication, journal title, pages)					
Technology:					
Checklist completed by:				Date:	
<b>SECTION 1: INTERNAL VALIDITY</b>					
<i>In a well conducted RCT study...</i>			<i>In this study this criterion is met:</i>		
RANDOM ALLOCATION OF SUBJECTS					
1.1	An appropriate method of randomization was used to allocate participants to intervention groups.	YES	NO	UNCLEAR	N/A
1.2	An adequate concealment method was used such that investigators, clinicians, and participants could not influence enrolment or intervention allocation.	YES	NO	UNCLEAR	N/A
1.3	The intervention and control groups are similar at the start of the trial. (The only difference between groups is the treatment under investigation.)	YES	NO	UNCLEAR	N/A
ASSESSMENT AND FOLLOW-UP					
1.4	Investigators, participants, and clinicians were kept 'blind' about treatment allocation and other important confounding/prognostic factors. If the answer is no, describe any bias that might have occurred.	YES	NO	UNCLEAR	N/A
1.5	The intervention and control groups received the same care apart from the intervention(s) studied.	YES	NO	UNCLEAR	N/A
1.6	The study had an appropriate length of follow-up.	YES	NO	UNCLEAR	N/A
1.7	All groups were followed up for an equal length of time (or the analysis was adjusted to allow for differences in length of follow-up).	YES	NO	UNCLEAR	N/A
1.8	What percentage of the individuals or clusters recruited into each group of the study dropped out	% drop out:			

	before the study was completed? What percentage did not complete the intervention(s)?	% did not complete intervention:			
1.9	All the subjects were analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	YES	NO	UNCLEAR	N/A
1.10	All relevant outcomes are measured in a standard, valid and reliable way.	YES	NO	UNCLEAR	N/A
1.11	The study reported only on surrogate outcomes. (If so, please comment on the strength of the evidence associating the surrogate with the important clinical outcome for this topic.)	YES	NO	UNCLEAR	N/A
1.12	The study uses a composite (vs. single) outcome as the primary outcome. If so, please comment on the appropriateness of the composite and whether any single outcome strongly influenced the composite.	YES	NO	UNCLEAR	N/A
<b>CONFLICT OF INTEREST</b>					
1.13	Competing interests of members have been recorded and addressed.	YES	NO	UNCLEAR	N/A
1.14	Views of funding body have not influenced the content of the study.	YES	NO	UNCLEAR	N/A
<b>SECTION 2: OVERALL STUDY APPRAISAL</b>					
2.1	How well was the study done to minimize bias? <i>Code Good, Fair, or Poor</i>	GOOD	FAIR	POOR	
2.2	If coded as Fair or Poor what is the likely direction in which bias might affect the study results?				
2.3	Are the results of this study directly applicable to the patient group targeted by this topic?	YES	NO	UNCLEAR	N/A
2.4	Other reviewer comments:				

Center for Evidence-based Policy 2009. Adapted from NICE and SIGN materials.

NEW YORK DEPARTMENT OF HEALTH		Quality Appraisal Checklist: Cohort Studies		
Study identification (Include author, title, year of publication, journal title, pages)				
Technology:				
Checklist completed by:				Date:
SECTION 1: INTERNAL VALIDITY				
<i>In a well conducted cohort study:</i>		<i>In this study the criterion is met:</i>		
1.1	The study addresses an appropriate and clearly focused question.	YES	NO	N/A
SELECTION OF SUBJECTS				
1.2	The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.	YES	NO	N/A
1.3	The study indicates how many of the people asked to take part did so in each of the groups being studied.	YES	NO	N/A
1.4	The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and accounted for in the analysis.	YES	NO	N/A
1.5	What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed?			
1.6	Comparison is made between full participants and those who dropped out or were lost to follow up, by exposure status.	YES	NO	N/A
ASSESSMENT AND FOLLOW-UP				
1.7	The study employed a precise definition of outcome(s) appropriate to the key question(s).	YES	NO	N/A
1.8	The assessment of outcome(s) is made blind to exposure status.	YES	NO	N/A
1.9	Where outcome assessment blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.	YES	NO	N/A
1.10	The measure of assessment of exposure is reliable.	YES	NO	N/A

1.11	Exposure level or prognostic factor is assessed more than once.	YES	NO	N/A
1.12	Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.	YES	NO	N/A
1.13	The study had an appropriate length of follow-up.	YES	NO	N/A
1.14	All groups were followed up for an equal length of time (or analysis was adjusted to allow for differences in length of follow-up)	YES	NO	N/A
<b>CONFOUNDING</b>				
1.15	The main potential confounders are identified and taken into account in the design and analysis.	YES	NO	N/A
<b>STATISTICAL ANALYSIS</b>				
1.16	Have confidence intervals been provided?	YES	NO	N/A
<b>CONFLICT OF INTEREST</b>				
1.17	Competing interests of members have been recorded and addressed.	YES	NO	N/A
1.18	Views of funding body have not influenced the content of the study.	YES	NO	N/A
<b>SECTION 2: OVERALL APPRAISAL OF THE STUDY</b>				
2.1	How well was the study done to minimize the risk of bias or confounding, and to establish a causal relationship between exposure and effect? <i>Code Good, Fair, or Poor</i>	GOOD	FAIR	POOR
2.2	If coded as Fair or Poor what is the likely direction in which bias might affect the study results?			
2.3	Are the results of this study directly applicable to the patient group targeted by this topic?	YES	NO	N/A
2.4	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study are you certain that the overall effect is due to the exposure being investigated?	YES	NO	N/A
2.5	Other reviewer comments:			

Center for Evidence-based Policy 2009. Adapted from NICE and SIGN materials.

<b>NEW YORK DEPARTMENT OF HEALTH</b>		<b>Quality Appraisal Checklist: Case Series</b>		
Study identification <i>(Include author, title, year of publication, journal title, pages)</i>				
Technology:				
Checklist completed by:				Date:
<b>SECTION 1: INTERNAL VALIDITY</b>				
1.1	The study addresses an appropriate and clearly focused question.	YES	NO	N/A
<b>SELECTION OF SUBJECTS</b>				
1.2	Were the patient characteristics clearly described?	YES	NO	N/A
1.3	Was the likelihood that some eligible subjects might have the outcome at the time of enrolment assessed and accounted for in the analysis (pertinent for screening and diagnostic topics)?	YES	NO	N/A
1.4	Was the study based on a consecutive sample or other clearly defined relevant population?	YES	NO	N/A
1.5	Did all of the individuals enter the study at a similar point in their disease progression?	YES	NO	N/A
<b>ASSESSMENT AND FOLLOW-UP</b>				
1.6	Were outcomes assessed using objective criteria (i.e., medical records) or was blinding used?	YES	NO	N/A
1.7	Was follow-up long enough for important events to occur?	YES	NO	N/A
1.8	Was there a low dropout or withdrawal rate (<20%)?	YES	NO	N/A
<b>CONFOUNDING</b>				
1.9	Were the main potential confounders identified and taken into account in the design and analysis?	YES	NO	N/A
<b>CONFLICT OF INTEREST</b>				
1.10	Competing interests of members have been recorded and addressed.	YES	NO	N/A
1.11	Views of funding body have not influenced the content of the study.	YES	NO	N/A

**SECTION 2: OVERALL APPRAISAL OF THE STUDY**

2.1	How well was the study done to minimize the risk of bias or confounding, and to establish a causal relationship between exposure and effect? <i>Code: Good, Fair, or Poor</i>	GOOD	FAIR	POOR
2.2	If coded as fair or poor, what is the likely direction in which bias might affect the study results?			
2.3	Are the results of this study directly applicable to the patient group targeted by this topic?	YES	NO	N/A
2.4	Other reviewer comments:			

Center for Evidence-based Policy 2009. Adapted from NICE and SIGN materials.

<b>NEW YORK DEPARTMENT OF HEALTH</b>		<b>Quality Appraisal Checklist: Crossover Studies</b>				
Study identification <i>(Include author, title, year of publication, journal title, pages)</i>						
Technology:						
Checklist completed by:				Date:		
<b>SECTION 1: INTERNAL VALIDITY</b>						
<i>In a well conducted Crossover study...</i>			<i>In this study this criterion is met:</i>			
RANDOM ALLOCATION OF SUBJECTS						
1.1	An appropriate method of randomization was used to allocate participants to intervention groups.		YES	NO	UNCLEAR	N/A
1.2	An adequate concealment method was used such that investigators, clinicians, and participants could not influence enrolment or intervention allocation.		YES	NO	UNCLEAR	N/A
1.3	The intervention and control groups are similar at the start of the trial. (The only difference between groups is the treatment under investigation.)		YES	NO	UNCLEAR	N/A
ASSESSMENT AND FOLLOW-UP						
1.4	Investigators, participants, and clinicians were kept 'blind' about treatment allocation and other important confounding/prognostic factors. If the answer is no, describe any bias that might have occurred.		YES	NO	UNCLEAR	N/A
1.5	The intervention and control groups received the same care apart from the intervention(s) studied.		YES	NO	UNCLEAR	N/A
1.6	The study had an appropriate length of follow-up.		YES	NO	UNCLEAR	N/A
1.7	All groups were followed up for an equal length of time (or the analysis was adjusted to allow for differences in length of follow-up).		YES	NO	UNCLEAR	N/A
1.8	What percentage of the individuals or clusters recruited into each group of the study dropped out		% drop out:			

	before the study was completed? What percentage did not complete the intervention(s)?	% did not complete intervention:			
1.9	All the subjects were analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	YES	NO	UNCLEAR	N/A

Center for Evidence-based Policy 2009. Adapted from NICE and SIGN materials.

<b>NEW YORK DEPARTMENT OF HEALTH</b>		<b>Quality Appraisal Checklist: Diagnostic Test Accuracy</b>			
Study identification <i>(Include author, title, year of publication, journal title, pages)</i>					
Technology:					
Checklist completed by:					Date:
<b>SECTION 1: INTERNAL VALIDITY</b>					
<b><i>In a well conducted study of diagnostic test accuracy...</i></b>			<b><i>In this study this criterion is met:</i></b>		
1.1	The spectrum of patients is representative of the patients who will receive the test in practice.	YES	NO	UNCLEAR	N/A
1.2	Selection criteria are clearly described.	YES	NO	UNCLEAR	N/A
1.3	The reference standard is likely to classify the condition correctly.	YES	NO	UNCLEAR	N/A
1.4	The period between reference standard and index test is short enough to be reasonably sure that the target condition did not change between the two tests.	YES	NO	UNCLEAR	N/A
1.5	The whole sample, or a random selection of the sample, received verification using a reference standard of diagnosis.	YES	NO	UNCLEAR	N/A
1.6	Patients received the same reference standard regardless of the index test result.	YES	NO	UNCLEAR	N/A
1.7	The reference standard was independent of the index test (i.e., the index test did not form part of the reference standard).	YES	NO	UNCLEAR	N/A
1.8	The execution of the index test was described in sufficient detail to permit replication of the test.	YES	NO	UNCLEAR	N/A
1.9	The execution of the reference standard was described in sufficient detail to permit replication of the test.	YES	NO	UNCLEAR	N/A

1.10	Index test results were interpreted without knowledge of the results of the reference standard.	YES	NO	UNCLEAR	N/A
1.11	Reference standard results were interpreted without knowledge of the results of the index test.	YES	NO	UNCLEAR	N/A
1.12	Uninterpretable or intermediate test results are reported.	YES	NO	UNCLEAR	N/A
1.13	An explanation is provided for withdrawals from the study.	YES	NO	UNCLEAR	N/A
CONFLICT OF INTEREST					
1.14	Competing interests of members have been recorded and addressed.	YES	NO	UNCLEAR	N/A
1.15	Views of funding body have not influenced the content of the study.	YES	NO	UNCLEAR	N/A
<b>SECTION 2: OVERALL STUDY ASSESSMENT</b>					
2.1	How well was the study done to minimize bias? <i>Code Good, Fair, or Poor</i>	GOOD	FAIR	POOR	
2.2	If coded as Fair or Poor what is the likely direction in which bias might affect the study results?				
2.3	Are the results of this study directly applicable to the patient group targeted by this topic?	YES	NO	UNCLEAR	N/A
2.5	Other reviewer comments:				

Center for Evidence-based Policy 2010. Adapted from NICE and SIGN materials, which are based on the QADAS tool: Whiting J, Rutjes AW, Dinnes J, et al. Development and validation of methods for assessing the quality of diagnostic accuracy studies. Health Tech Assess 2004; 8(25):1 - 234.

<b>NEW YORK DEPARTMENT OF HEALTH</b>		<b>Quality Checklist: Economic Evaluations</b>			
Study citation (Include last name of first author, title, year of publication, journal title, pages)					
Technology:					
Checklist completed by:				Date:	
<b>SECTION 1: APPLICABILITY</b>					
<b><i>In a well conducted economic study...</i></b>			<b><i>In this study the criterion is met:</i></b>		
1.1	The results of this study are directly applicable to the patient group targeted by this key question.	YES	NO	UNCLEAR	N/A
<i>If criterion 1.1 is rated no, the study should be excluded.</i>					
1.2	The healthcare system in which the study was conducted is sufficiently similar to the system of interest in the topic key question(s).	YES	NO	UNCLEAR	N/A
<b>SECTION 2: STUDY DESIGN, DATA COLLECTION, AND ANALYSIS</b>					
<b><i>In a well conducted economic study...</i></b>			<b><i>In this study the criterion is met:</i></b>		
2.1	The research question is well described.	YES	NO	UNCLEAR	N/A
2.2	The economic importance of the research question is stated.	YES	NO	UNCLEAR	N/A
2.3	The perspective(s) of the analysis are clearly stated and justified (e.g. healthcare system, society, provider institution, professional organization, patient group).	YES	NO	UNCLEAR	N/A
2.4	The form of economic evaluation is stated and justified in relation to the questions addressed.	YES	NO	UNCLEAR	N/A
2.5	<i>Circle one</i>	YES	NO	UNCLEAR	N/A

	<p>a. Details of the methods of synthesis or meta-analysis of estimates are given (if based on a synthesis of a number of effectiveness studies).</p> <p>b. Details of the design and results of effectiveness study are given (if based on a single study).</p>				
2.6	Estimates of effectiveness are used appropriately.	YES	NO	UNCLEAR	N/A
2.7	Methods to value health states and other benefits are stated.	YES	NO	UNCLEAR	N/A
2.8	Outcomes are used appropriately.	YES	NO	UNCLEAR	N/A
2.9	The primary outcome measure for the economic evaluation is clearly stated.	YES	NO	UNCLEAR	N/A
2.10	Details of the subjects from whom valuations were obtained are given.	YES	NO	UNCLEAR	N/A
2.11	Competing alternatives are clearly described.	YES	NO	UNCLEAR	N/A
2.12	All important and relevant costs for each alternative are identified.	YES	NO	UNCLEAR	N/A
2.13	Methods for the estimation of quantities and unit costs are described.	YES	NO	UNCLEAR	N/A
2.14	Quantities of resource use are reported separately from their unit costs.	YES	NO	UNCLEAR	N/A
2.15	Productivity changes (if included) are reported separately.	YES	NO	UNCLEAR	N/A
2.16	The choice of model used and the key parameters on which it is based are justified.	YES	NO	UNCLEAR	N/A
2.17	All costs are measured appropriately in physical units.	YES	NO	UNCLEAR	N/A
2.18	Costs are valued appropriately.	YES	NO	UNCLEAR	N/A

2.19	Outcomes are valued appropriately.	YES	NO	UNCLEAR	N/A
2.20	The time horizon is sufficiently long enough to reflect all important differences in costs and outcomes.	YES	NO	UNCLEAR	N/A
2.21	The discount rate(s) is stated.	YES	NO	UNCLEAR	N/A
2.22	An explanation is given if costs and benefits are not discounted.	YES	NO	UNCLEAR	N/A
2.23	The choice of discount rate(s) is justified.	YES	NO	UNCLEAR	N/A
2.24	All future costs and outcomes are discounted appropriately.	YES	NO	UNCLEAR	N/A
2.25	Details of currency of price adjustments for inflation or currency conversion are given.	YES	NO	UNCLEAR	N/A
2.26	Incremental analysis is reported or it can be calculated from the data.	YES	NO	UNCLEAR	N/A
2.27	Details of the statistical tests and confidence intervals are given for stochastic data.	YES	NO	UNCLEAR	N/A
2.28	Major outcomes are presented in a disaggregated as well as aggregated form.	YES	NO	UNCLEAR	N/A
2.29	Conclusions follow from the data reported.	YES	NO	UNCLEAR	N/A
2.30	Conclusions are accompanied by the appropriate caveats.	YES	NO	UNCLEAR	N/A

### SECTION 3: SENSITIVITY ANALYSIS

<i>In a well conducted economic study...</i>		<i>In this study the criterion is met:</i>			
3.1	The approach to sensitivity analysis is given.	YES	NO	UNCLEAR	N/A
3.2	All important and relevant costs for each alternative are identified.	YES	NO	UNCLEAR	N/A
3.3	An incremental analysis of costs and outcomes of alternatives is performed.	YES	NO	UNCLEAR	N/A

3.4	The choice of variables for sensitivity analysis is justified.	YES	NO	UNCLEAR	N/A
3.5	All important variables, whose values are uncertain, are appropriately subjected to sensitivity analysis.	YES	NO	UNCLEAR	N/A
3.6	The ranges over which the variables are varied are justified.	YES	NO	UNCLEAR	N/A
<b>SECTION 4: CONFLICT OF INTEREST</b>					
<b><i>In a well conducted economic study...</i></b>		<b><i>In this study the criterion is met:</i></b>			
4.1	Competing interests of members have been recorded and addressed.	YES	NO	UNCLEAR	N/A
4.2	Views of funding body have not influenced the content of the study.	YES	NO	UNCLEAR	N/A
<b>SECTION 5: OVERALL ASSESSMENT</b>					
5.1	How well was the study done to minimize bias? <i>Code: Good, Fair or Poor</i>	GOOD	FAIR	POOR	
5.2	If coded as fair or poor, what is the likely direction in which bias might affect the study results?				
5.3	Other reviewer comments:				

Center for Evidence-based Policy 2011. Adapted from BMJ, NICE, and the Consensus on Health Economic Criteria (CHEC).