

SCOTT & WHITE/SWHP TECHNOLOGY ASSESSMENT OVERVIEW & INTRODUCTION

The Scott & White and Scott & White Health Plan (SWHP) Technology Assessment Committee evaluates the clinical efficacy, safety, cost, and fee information for new, replacement or uncovered medical and behavioral procedures, treatments, devices or equipment. This assessment is used to evaluate not only the efficacy, safety, and cost effectiveness of the new procedures, devices or treatments, but also for consideration for coverage under SWHP and review of other coverage determinations made by other major insurers.





The current standing committee consists of the Scott and White Memorial Hospital (SWMH) Chief Medical Officer, SWHP Chief Medical Officer, SWHP Medical Directors, SWHC Chief Operation Officer, SWHC Chief Medical Officer, SWHC Associate Chief Medical Officer, SWHP Medical Director for System Improvement, SWHC Chairman of Department of Medicine, SWHC Chairman of Department of Orthopedic Surgery, SWHC Chairman of Department of Surgery, Hillcrest Baptist Medical Center Chief Medical Officer and Executive Vice President, Scott and White Healthcare - Round Rock Chief Medical Officer, SWHC Chief Financial Officer, SWHC Vice President, Pharmacy Services, SWHC Vice President, Supply Chain Services, SWHC Vice President, Managed Care/Financial Planning, SWHC Vice President Revenue Cycle Operations Hospital Division, SWHC Chief Nursing Executive/SWMH Chief Nursing Officer, SWHP Associate Vice President - Medical Services

The Technology Assessment Committee requests that you (the Provider that is most directly involved and/or appears to be the one that will use the technology under assessment), to complete the attached forms and analysis for their consideration during the technology/new procedure assessment.

Information and/or questions to be submitted to:
Garrett, Director of Health Services, SWHP
Phone/email 254-298-3085/ degarrett@swmail.sw.org

Debbie

There are five separate tabs in this Excel workbook, and please complete all required information. Dynamic links to separate tabs for 4 of the 5 pages are as follows:

-  Checklist
-  New Procedure Form
- Additional Information (not hyperlinked)
-  FMEA Worksheet
-  FMEA Training Tool

The completed forms and other supporting information are to be timely submitted electronically or via mail to Debbie Garrett a **minimum of ten business days prior** to the scheduled Technology Assessment Committee meeting.

LAST DATE REVISED/UPDATED	12/5/2011
DATE LAST TAC COMMITTEE REVIEWED/APPROVED	12/15/2011
DATE LAST UM COMMITTEE REVIEWED/APPROVAL	12/8/2011
DATE LAST QIS COMMITTEE REVIEW/APPROVAL	12/13/2011

**SCOTT & WHITE/SWHP
TECHNOLOGY ASSESSMENT
CHECKLIST OF INFORMATION AND
ANALYSIS REQUIRED**

DONE

1 Scott and White Health Plan (SWHP)TAC will utilize evidence-based reports from Haye's Technology Assessment, Inc. for review analysis and recommendations regarding SWHPcoverage determinations. If Haye's does not have a review, the requesting physician/specialty service will be required to submit a minimum of three well-designed and well-conducted clinical investigations published in peer review journals to include:

- o Medical evidence to support that the new technology can measure or alter the physiologic changes related to disease, illness or condition.
- o Medical evidence that based upon medical facts, the new technology positively affects the health outcome of the patient.

2 Completion of the New Procedure Form and Required General Information Sections .

3 Completion of the FMEA worksheet, if applicable.

4 Submit completed forms and other supporting information to Debbie Garrett, Director of Health Services, SWHP electronically or in the mail at a **minimum of 10 business days prior to the scheduled Technology Assessment Committee Meeting.**

LINK TO OVERVIEW PAGE



**SCOTT & WHITE/SWHP
TECHNOLOGY ASSESSMENT
NEW PROCEDURE FORM**

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0
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NOTE: Please enter information on lines or shaded areas provided. Should additional space be needed, please make reference to attached information.

Name of procedure(medical/surgical) or behavioral health treatment/technology/device/equipment (Enter on New Procedure Form):

ENTER NAME ON NEW PROCEDURE FORM

Name of Department (Individual and/or Group) making the application:

ENTER DEPT ON NEW PROCEDURE FORM

Please Check One

YES

NO

1 Has the procedure been used elsewhere?

If YES, please include details here:

YES

NO

2 Does this new procedure replace current procedures?

If YES, please include details here:

3 If YES to 2, does the new procedure have advantages over the current procedures?

YES

NO

If YES, please include details here:

**SCOTT & WHITE/SWHP
TECHNOLOGY ASSESSMENT
NEW PROCEDURE FORM**

Please Check One

YES

NO

4 Has the procedure been evaluated elsewhere?

If YES, please include details here:

If YES, please attach and list a minimum of three clinical investigations conducted in peer reviews:

5 If the procedure involves the use of a new medical device, has the device been approved for this purpose by the following (Refer to additional device questions at number 11):

YES

NO

FDA

Medicare

Other:

Other:

Please attach support.

6 Are there any training requirements for the proposed new procedure or equipment?

YES

NO

If YES, please include details here:

**SCOTT & WHITE/SWHP
TECHNOLOGY ASSESSMENT
NEW PROCEDURE FORM**

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7 Has a patient information or education sheet and/or plan been developed?

Please Check One	
YES	NO
<input type="checkbox"/>	<input type="checkbox"/>

If YES, please attach support.

8 How will outcomes be monitored?

Please include details here:

9 If the procedure carries with it a risk for adverse events are there criteria for reviewing outcomes before further procedures are performed?

YES	NO
<input type="checkbox"/>	<input type="checkbox"/>

If YES, please complete FMEA WORKSHEET and include other details here:

Link to FMEA Worksheet here: [\[redacted\]](#)

**SCOTT & WHITE/SWHP
TECHNOLOGY ASSESSMENT
NEW PROCEDURE FORM**

10 Is there any additional follow-up care required for the new procedure?

	<u>Please Check One</u>	
	YES	NO
	<input type="checkbox"/>	<input type="checkbox"/>

If YES, please include details here:

11 As discussed in 5, if this new procedure includes a new medical device (product), briefly describe this product:

12 Is there a current in-house product now performing the same function or procedure?

	YES	NO
	<input type="checkbox"/>	<input type="checkbox"/>

If YES, please include details here:

**SCOTT & WHITE/SWHP
TECHNOLOGY ASSESSMENT
NEW PROCEDURE FORM**

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Please Check One

13 Will the requested new product replace or supplement current in-house products?

YES

NO

If YES, please include details here:

14 What other departments will use or be affected by this product?

YES

NO

Please include details here:

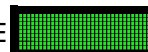
15 Are there resident & other training education issues to consider for approving this procedure/device?

YES

NO

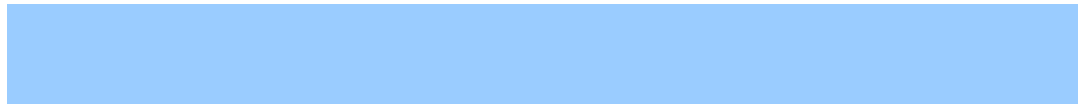
Please include details here:

LINK TO OVERVIEW PAGE

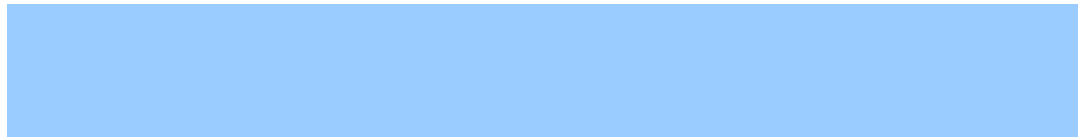


**SCOTT & WHITE/SWHP
TECHNOLOGY ASSESSMENT
ADDITIONAL INFORMATION**

Are other payors providing coverage for this new procedure/treatment? If so, who and under what terms?



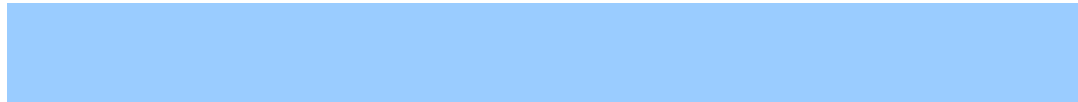
Are there any facts not provided elsewhere in this format that you wish to highlight to the Committee regarding your coverage request?



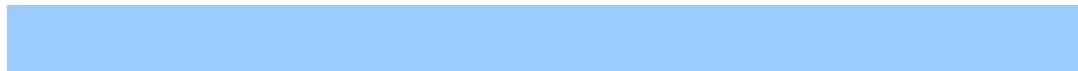
Please include any known CPT/HCPCS and/or associated billing codes



Please provide some idea of the cost for the new product, device, drug, service, procedure, etc. under review



Please provide any comparative costs for current similar services, devices, etc.



SCOTT & WHITE/SWHP TECHNOLOGY ASSESSMENT Failure Mode and Effect Analysis (FMEA): *Training Tool*

LINK TO OVERVIEW PAGE 

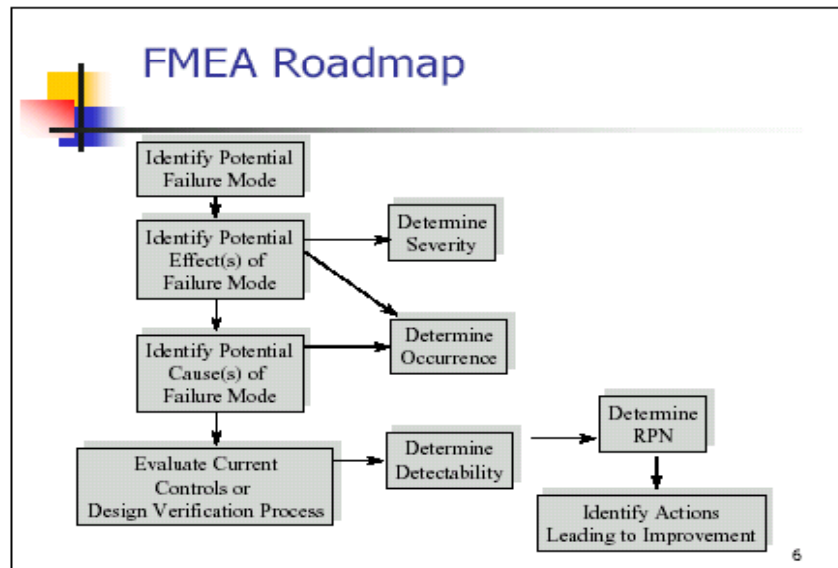
What's an "FMEA"?

An FMEA (failure mode and effect analysis) is the structured analysis of a system or process with the intent to prevent failures *prior to* their occurring, and documents the actions taken by an organization to minimize the risks of failures.

In an FMEA, each individual failure is considered as an independent occurrence with no relation to other failures in the system. FMEA's identify single failure modes that either directly result in or contribute significantly to an accident.

The general steps within a simple FMEA are:

- Identifying the role of each component in process (a "functional analysis")
- Identifying each type or mode of failure
- Identifying the causes & effects of each failure
- Identifying existing safeguards/controls against the failure
- Prioritize actions leading to improvement



Adapted from: <http://www.fmeainfocentre.com>

Goal

Through use of the FMEA method, our goal is to identify actions needed to improve the selected “process” we focus on.

Specific Steps in the FMEA Analysis

PHASE 1

- 1 Identifying a system, operation, or process to analyze
- 2 Identifying each step or part of the process. (Typically a flow chart)
- 3 Identifying the role or function of each of the process steps (This is called a “functional analysis” – using a separate FMEA worksheet to analyze each process step).
- 4 Identifying the potential or known failures that may occur at each step. Failure modes typically occur when a function is not performed.
- 5 Identifying the effects of each failure mode.
- 6 Identifying the causes of each failure mode.
- 7 Prioritizing the identified failure modes based on the frequency of occurrence (OC).
- 8 Prioritizing the identified failure modes based on severity (SV).
- 9 Prioritizing the identified failure modes based on the likelihood of detection (DT) with existing controls.
- 10 Calculation of a Risk Priority Number (using items 7, 8, & 9)
- 11 Providing for follow-up corrective and preventive actions, prioritized by Risk Priority Number, with an assigned person.
12. Re-analysis of Risk Priority Number after actions are taken (“action results”).

Completing the FMEA Worksheet – First 8 columns only

Column 1: FAILURE MODE

Describe what kind of failures might occur. Begin with a “failure” of skipping the step entirely. Consider other failures such as incomplete performance of the step, or inaccurate completion of the step. Think about the failures that could be the most severe first. Also, think about failures that might commonly occur. (free text)

Column 2: EFFECTS OF FAILURE

What are the initial results of this failure? The end results if not caught? (free text)

Column 3: SEVERITY

How severe of an effect is that, on a 1-10 scale?

Severity is a rating corresponding to the seriousness of an effect of a potential failure mode. (scale: 1-10. 1: no effect on output, 5: moderate effect, 8: serious effect, 10: hazardous effect)

Column 4: CAUSES OF FAILURE

What are the common causes of this failure? (free text)

Column 5: OCCURRENCE

How often is this failure likely to occur, on a 1-10 scale?

Occurrence is a rating corresponding to the rate at which a first level cause and its resultant failure mode will. (scale: 1-10. 1: failure unlikely, 5: occasional failure, 8: high # of failures likely, 10: failures certain)

Column 6: CURRENT CONTROLS/SAFEGURDS

Describe what processes (controls or safeguards) we have in place to detect this failure before it reaches the patient. Safeguards are the equipment, procedures, and administrative controls in place to help (1) prevent the failure from occurring or (2) lessen the effects if the situation does occur. (free text)

Column 7: DETECTION/FAIL DETECTION

How likely are current controls to detect the failure, on a 1-10 scale?

Detection is a rating corresponding to the likelihood that the detection methods or current controls will detect the potential failure mode before the process reaches the patient (scale: 1-10. 1: will detect failure, 5: might detect failure, 10: almost certain not to detect failures)

Column 8: Calculating Risk Priority Number (RPN)

The RPN identifies the greatest areas of concern.

It comprises the assessment of the:

- (1) Severity rating,
- (2) Occurrence rating, and
- (3) detection rating for a potential failure mode.

RPN = Severity Rating x Occurrence Rating x Detection Rating

The highest possible RPN is $10 \times 10 \times 10 = 1000$

Guidelines for Applying 1-10 Rank Scores for Severity, Occurrence, & Detection

SEVERITY (S)

Effect	Ranking
Hazardous without warning	10
Hazardous with warning	9
Very High	8
High	7
Moderate	6
Low	5
Very Low	4
Minor	3
Very Minor	2
None	1

Occurrence (O)

Probability of Failure	Possible Failure Rates	Ranking
Very High: Failure is almost inevitable	≥1 in 2	10
	1 in 3	9
High: Repeated Failures	1 in 8	8
	1 in 20	7

Moderate: Occasional Failures	1 in 80	6
	1 in 400	5
	1 in 2,000	4
Low: Relatively Few Failures	1 in 15,000	3
	1 in 150,000	2
Remote: Failure is Unlikely	≤1 in 1,500,000	1

Detection (D)

Detection	Criteria: Likelihood of Detection by Design Control	Ranking
Absolute Uncertainty	Current controls will not and/or cannot detect a potential cause/mechanism and subsequent failure mode; or there is no Design Control.	10

Very Remote	Very remote chance the current controls will detect a potential cause/mechanism and subsequent failure mode.	9
Remote	Remote chance the current controls will detect a potential cause/mechanism and subsequent failure mode.	8
Very Low	Very Low chance the current controls will detect a potential cause/mechanism and subsequent failure mode.	7
Low	Low chance the current controls will detect a potential cause/mechanism and subsequent failure mode.	6

Moderate	Moderate chance the current controls will detect a potential cause/mechanism and subsequent failure mode.	5
Moderately High	Moderately high chance the current controls will detect a potential cause/mechanism and subsequent failure mode.	4
High	High chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	3
Very High	Very High chance the Design Control will detect a potential cause/mechanism and subsequent failure mode	2

Almost Certain

Design Control will almost certainly detect a potential cause/mechanism and subsequent failure mode

1