Anthem

Medical Policy

Subject: Automated Evacuation of Meibomian Gland
Document #: MED.00103
Status: Reviewed
Publish Date: 09/27/2023
Last Review Date: 08/10/2023

Description/Scope

This document addresses the use of devices (and associated imaging) which automate the process of applying heat and intermittent pressure for the treatment of meibomian gland dysfunction.

Position Statement

Investigational and Not Medically Necessary:

The use of an automated evacuation device using heat and intermittent pressure, and associated tear film imaging, is considered **investigational and not medically necessary** for the treatment of meibomian gland dysfunction.

Rationale

Meibomian gland dysfunction is a condition in which the glands either don't secrete enough oil or secrete oil of poor quality. Meibomian gland dysfunction can cause symptoms of dry eye and inflammation of the eyelid. If the glands become blocked with thick secretions, the clogged glands may be unable to secrete oil. This can lead to permanent changes in the tear film and dry eyes. Symptoms may include burning, itching, crustiness, watery eyes, and sensitivity to light. Treatment may include artificial tear drops, antibiotic eye drops, and warm compresses with or without massage to the eyelids. Automated devices which combine the process of warm compresses and massage have been proposed as a treatment for meibomian gland dysfunction.

Goto and colleagues (2002) reported on the safety and short-term efficacy of an infrared warm compression device used in 37 subjects with a diagnosis of non-inflamed meibomian gland dysfunction. Subjective symptom scores, face scores, tear evaporation rates, fluorescein and rose bengal vital staining, tear break-up time, Schirmer test, meibomian gland obstruction, and meibography were compared before and after 2 weeks of treatment. Following 2 weeks of treatment, total symptom scores improved from 12.3 to 8.4. Face scores improved from 7.0 to 5.3. Tear evaporation rates did not change significantly after treatment, but evaporation during forced blinking decreased from 22.1 to 16.2. Improvement of scores was also noted in fluorescein and rose bengal vital staining, tear break-up time in seconds, Schirmer test and meibomian gland obstruction. No change was noted in meibography score before and after treatment. The authors concluded that the infrared warm compression device was safe and effective for the meibomian gland dysfunction after 2 weeks of treatment. However, the treatment in this study was limited to non-inflamed meibomian gland dysfunction. The authors have no experience with this treatment for meibomian gland dysfunction with active inflammation and conclude longer term studies would be required.

In 2006, Matsumoto reported the evaluation of safety and efficacy of a warm moist air device on tear functions and meibomian gland dysfunction. In a short-term study, 15 individuals with simple meibomian gland dysfunction and 20 control individuals were enrolled to evaluate the safety and short-term effects of a warm moist air device. All individuals underwent moist warm air applications for 10 minutes. Visual analog scores were used to measure symptoms of ocular surface fatigue, changes in tear functions and ocular surface status. Tear film break-up time measurements were obtained along with Schirmer test 1, fluorescein staining scores and rose bengal staining scores. After the initial study, another longer-term clinical trial was started. Ten individuals with simple meibomian gland dysfunction received warm moist air treatment for 2 weeks and another 10 individuals with simple meibomian gland dysfunction received warm towel compresses for 2 weeks. Treatment was performed for 10 minutes twice a day for 2 weeks. Visual analog scores, tear film break-up time measurements, fluorescein and rose bengal staining scores were measured before and 24 hours after each treatment. Visual analog scores showed improvement with warm moist air application in the short-term study and in both the warm moist air device and warm compress application groups after 2 weeks. Tear film break-up time improved from 3.9 seconds to 10.9 seconds in the individuals with meibomian gland dysfunction with warm moist air application in the short-term study. The tear film time did not change significantly in the control group. Schirmer test, fluorescein and rose bengal staining scores did not show significant changes with warm moist air application in the short-term study, nor did it change in the warm moist air device or warm compress groups after 2 weeks.

Friedland and colleagues (2011) reported on 14 individuals with a prior diagnosis of meibomian gland dysfunction during an open label, multi-center trial where participants received a 12-minute treatment with an automated device that delivers heat and massage along the eyelids from the terminal ends of the meibomian glands to the meibomian gland orifices. Automated treatment was given to both eyes in succession. There was no control group; however, individuals also received additional expression on one eye only with a handheld instrument which was manipulated against the inner surface of the lower eyelid while the meibomian glands were manually expressed with the thumb or index finger. The purpose of the automated device is to soften the obstruction with heat and express the obstruction with pulsatile pressure. Subjects were evaluated at baseline and following treatment at 1 week, 1 month and 3 months. Individuals were observed for the number of meibomian glands yielding liquid secretion, tear film break-up time, corneal fluorescein staining, dry eye symptoms, and discomfort or pain during the treatment. The mean number of meibomian glands yielding liquid secretion increased from 2.9 at baseline to 9.9 at 3 months. Tear film break-up time on average increased from 5.2 seconds at baseline to 11.0 seconds at 3 months. On average, corneal fluorescein staining decreased from 0.6 seconds to 0.1 seconds at 3 months. Dry eye symptoms were measured using the Standard Patient Evaluation of Eye Dryness (SPEED) questionnaire. The SPEED score decreased on average from 16.2 at baseline to 7.8 at 3 months. During the automated treatment, discomfort scores were reported as 2.3-2.4 and they were reported as 3.7 during the handheld device. One individual received only 10.5 minutes of treatment with the automated device as it was stopped due to discomfort.

An industry sponsored, open-label single-crossover, multicenter trial (Lane 2012) compared the LipiFlow™ (TearScience®, Morrisville, NC) automated office-based device with standardized warm compress using the iHeat (Advanced Vision Research, Woburn, MA) portable warm compress system. The LipiFlow device is designed to relieve obstruction of the meibomian glands with the application of heat and graded pulsatile pressure to the upper and lower eyelids. The study compared the outcomes of 139 subjects with meibomian gland dysfunction randomized to either LipiFlow (treatment group; n=69) or warm compresses (control group; n=70). The LipiFlow group received a 12-minute LipiFlow treatment and was examined at day 1, 2 weeks and 4 weeks. Control subjects received

a 5-minute iHeat warm compression treatment with instructions to perform the same treatment daily for 2 weeks. After 2 weeks, 68 individuals from the control group (warm compresses) crossed over and then received treatment via the automated LipiFlow device. Primary outcome effectiveness was measured by assessment of meibomian glands (using a handheld instrument) and tear break-up time. Secondary outcomes were measured with the SPEED and Ocular Surface Disease Index (OSDI) questionnaires. After 2 weeks, the individuals receiving the LipiFlow treatment showed an increase from baseline in the metrics of meibomian gland secretion characteristics and increase in tear break-up time. There was no significant change in those measures in the control group. After crossover at 2 weeks, the 68 control subjects who then received the LipiFlow treatment also showed an increase in meibomian gland secretion characteristics. This study did not include a group receiving warm compresses only for 4 weeks. It is notable that although the control group did not show significant increases in meibomian gland and tear film metrics at 2 weeks, the control group did have a significant reduction in self-reported dry eye symptom frequency and severity. Also, the control group was limited to 5 minutes of warm compression therapy once a day, while typical treatment for meibomian gland dysfunction consists of hot packs 3 to 4 times daily along with lid margin scrubs.

A study by Finis and colleagues (2014a) reported on participants who were randomized to receive either a single LipiFlow treatment or a participant-performed twice-daily lid warming and massage for 3 months. Participants were evaluated before treatment and at 1 and 3 months following treatment. A total of 31 participants completed the 3-month follow-up. At 1 and 3 months, the participants in the LipiFlow treatment group had a reduction in OSDI scores compared with those in the lid warming and massage group. Both treatments were found to have a significant improvement in expressible meibomian glands compared to the baseline parameters, but no significant difference was noted between the two groups. While the study showed that a single LipiFlow treatment is at least as effective as a 3-month lid margin hygiene regimen, this study was observer-masked only and a placebo effect may have confounded improvements in subjective symptoms.

Blackie and colleagues (2016) conducted an open-label clinical trial to measure the long-term effectiveness of vectored thermal pulsation (VTP) LipiFlow treatment in improving meibomian gland function and dry eye symptoms in affected participants. In this 12-month study, 200 participants (400 eyes, age range 22-85 years) were randomized into a treatment group (n=101) using a single VTP device 2 times daily for 3 months, and a control group (n=99) using conventional warm compress and eyelid hygiene therapy. The authors compared the meibomian gland secretion (MGS) and the mean OSDI score at 12 months between the control and treatment groups. At 3 months, the control group participants crossed over to receive VTP treatments. The effectiveness on MGS and dry eye symptoms was assessed at baseline and at 1, 3, 6, 9, and 12 months. The treatment group had greater mean improvement in MGS ($p<0.0001$) and dry eye symptoms ($p=0.0068$) at the 3-month interval compared to the control group. Compared to the control group, at 3 months the treatment group had a greater MGS mean improvement ($p<0.0001$) and dry eye symptoms ($p=0.0068$). At 12 months, 86% of the treatment had a sustained MGS mean improvement from 6.4 ± 3.7 at baseline to 17.3 ± 9.1 ($p<0.0001$) and dry eye symptoms from 44.1 ± 20.4 to 21.6 ± 21.3 ($p<0.0001$). At 12 months, 89% of the crossover group had a sustained MGS mean improvement from 6.3 ± 3.6 to 18.4 ± 11.1 ($p<0.0001$) and dry eye symptoms from 49.1 ± 21.0 to 24.0 ± 23.2 ($p<0.0001$). A greater MGS mean improvement was related to a less severe condition at baseline ($p=0.0017$) and reduced time between diagnosis and treatment ($p=0.0378$). The authors concluded that the use of VTP for MGD reduced symptoms and provided prolonged relief. Of note, study subjects were 97% Caucasian, 71% female and the lead authors were affiliated with TearScience, Inc, the manufacturer of LipiFlow.

A 2018 prospective, randomized, parallel-group study by Hagen and colleagues enrolled 28 participants with moderate-to-severe meibomian gland dysfunction. The participants were randomized to receive either doxycycline treatment (n=14) or VTP (using the LipiFlow System). The oral doxycycline was given daily for 3 months and the VTP was given once in a single bilateral 12-minute procedure. Any adjunctive treatment (for example, artificial tears, fish oil supplements, lid scrubs, and warm compresses) was continued as long as it had been used for at least 3 months prior to the doxycycline or VTP. Primary endpoint was evaluation of dry eye symptoms using a standard dry eye questionnaire (the Standard Patient Evaluation for Eye Dryness [SPEED]) and meibomian gland function assessed by counting the number of glands yielding liquid secretion (meibomian glands yielding liquid secretion [MGYLS]), tear breakup time, and corneal and conjunctival staining. In the doxycycline group, 2 participants discontinued their treatment due to intolerance to study medication. In the VTP group, 1 participant was lost to follow-up. These participants were not included in the final analysis. In the VTP group, the SPEED scores, MGYLS and tear breakup time were improved from their baseline levels. There was also improvement in the corneal and conjunctival staining. In the doxycycline group, SPEED scores, MGYLS and conjunctival stain improved significantly from the pretreatment levels, but improvement in tear breakup time and corneal stain did not reach statistical significance. While the results show improvement using the VTP compared to the oral doxycycline, there was no comparison of the VTP to a conventional method of lid warming and massage. Further studies are necessary with comparison of the automated process to a manual process to determine efficacy of the automated process.

Meibomian gland dysfunction can be classified into two categories based on meibomian gland secretion; low-delivery and high-delivery states. Low-delivery states are further classified as hyposecretory meibomian gland dysfunction (HGMD) and obstructive meibomian gland dysfunction (OMGD). HGMD is decreased meibum delivery with abnormalities in the meibomian glands without obstruction. OMGD is caused by obstruction or altered secretion. Both types have a decrease in meibum secretion. A 2020 interventional study by Li and colleagues reported on the use of LipiFlow to treat OMGD (n=25 participants) and HMGD (n=25 participants), evaluating the efficacy over a 12-week period. Efficacy was assessed using SPEED scores, OSDI scores, Schirmer I test (SIT), noninvasive keratographic breakup time (NIKBUT), tear meniscus height (TMH), lipid layer thickness (LLT), and partial blink rate (PBR). Compared to baseline, the SPEED and OSDI scores decreased in both OMGD and HMGD groups after 12 weeks. In both groups, mean NIKBUT and TMH increased at the 4-week point, and gradually decreased until the 12-week point. SIT improved in both groups at 4 weeks then gradually decreased until the 12-week point. LLT peaked at 4 weeks and gradually decreased in both groups. The PBR also decreased in both groups. There was overall improvement in both groups following treatment, however there was greater improvement noted in the OMGD group compared to the HMGD group. While this study shows improvement in participants with both OMGD and HMGD, lack of a control group makes it difficult to determine efficacy of an automated process compared to a manual process for treatment of meibomian gland dysfunction.

A 2021 retrospective review by Chester and colleagues reported on the efficacy of a wearable eyelid device (designed to melt and clear obstructions) in treating signs and symptoms of meibomian gland disease over a 3 month period. Assessments were made by using the SPEED questionnaire and meibomian gland expression (MGE) scores pre-treatment and at 8 and 12 weeks following treatment. There were 92 subjects included. Median pre-treatment SPEED total score was 16.0 compared to 9.0 post-treatment. From pre-treatment to post-treatment, median MGE score increased from 5.0 to 9.0 in the right eye and 4.0 to 9.0 in the left eye. Median MGE scores for individual quadrants ranged from 1.0 to 2.0 pre-treatment versus 3.0 post-treatment. Limitations include the retrospective design which lacks a control group or comparison to manual methods of meibomian gland evacuation.

In a 2022 systematic review and meta-analysis by Hu and colleagues, the authors reported on 10 randomized clinical trials which compared an automated meibomian gland evacuation device to lid hygiene, placebo, or no treatment. One of the trials used a paired-eye design, 4 trials had a parallel-group design, and 5 trials used a crossover design. The interventions varied across the trials. There were 9/10 trials which used OSDI or SPEED questionnaires to assess subjective symptoms. There were 7/10 trials which assessed meibomian glands using MGYLS, meibomian glands yielding secretion score (MGYSS), or LLT. Objective symptoms were assessed in 8/10 studies. Adverse events or intraocular pressure was reported in 9/10 trials. There were 9 studies assessed as having a high

risk of bias, determined by 6 trials being industry-sponsored or by the author being associated with the research company. Five of the trials used a cross-over design, but there was no washout period, and baselines were not equivalent between groups in 1 of the trials. Also, 1 study stated randomization was generated with a random number table and envelopes. None of the other studies had details about randomization. Since the interventions varied among the 10 trials, the trials were grouped into 2 comparisons: Lipiflow treatment (± lid hygiene) versus lid hygiene alone (8 trials) and Lipiflow versus no treatment (2 trials). Analysis of the trials showed the Lipiflow treatment could improve symptoms with no significant adverse effects. However, due to the high risk of bias and lack of blinding methods in the studies, caution should be used in interpreting efficacy results. Large-scale, well-designed, non-sponsored randomized clinical trials should be completed.

Meng and colleagues (2023) reported the results of a prospective, randomized, observer-masked trial which evaluated the efficacy of automated thermal pulsation compared to warm compresses and eyelid massage for treatment of meibomian gland dysfunction. There were 50 eyes in the automated thermal pulsation group and 50 eyes in the warm compress group. Those in the automated thermal pulsation group received a single treatment while those in the warm compress group underwent treatment daily for 2 weeks. Subjective efficacy was measured by SPEED questionnaire. Objective measurements were done by MGYLS, MGS score, LLT, tear break-up time (TBUT), and corneal fluorescein staining (CFS) at baseline and 3 months after treatment. SPEED score in the automated thermal pulsation group was 7.08 ± 2.70 at baseline, 7.08 ± 2.70 at 1 month, 4.25 ± 2.00 at 2 months, and 3.84 ± 1.49 at 3 months after treatment. In the warm compress group, baseline SPEED score was 7.20 ± 2.16, 7.20 ± 2.16 at 1 month, 6.64 ± 2.78 at 2 months, and 6.56 ± 2.77 at 3 months after treatment. In the automated group, TBUT increased from 2.31 ± 0.96 at baseline to 5.58 ± 2.19 at 3 months. In the warm compress group TBUT increased from 2.67 ± 1.44) at baseline to 3.96 ± 1.89 at 3 months. MGYLS number, MGS score, LLT improved in the automated group and continued through the 3 month follow-up. In the warm compress group, CFS showed a significant improvement at 1 month when compared to the automated group. While the automated group showed improvements compared to the manual treatment, the small number of participants, short duration of follow-up (3 month) and lack of participant masking weaken the reliability of these results.

Additional studies are now looking at the use of an automated process to prevent dry eye and meibomian gland dysfunction caused by cataract surgery. In a 2021 study by Zhao and colleagues, the authors reported the efficacy of preoperative VTP therapy prior to cataract surgery. Participants were followed for 3 months after treatment. The primary outcome measure was an improvement in MGYLS. Efficacy was measured using symptoms of dry eye, LLT, TBUT, corneal staining, SIT, MGYLS, and meibomian gland dropout. There were 32 participants previously diagnosed with meibomian gland dysfunction enrolled. Each participant received VTP on one eye. Of the 32 participants, 16 had cataract surgery following VTP and 16 received only VTP and did not have surgery. Scores from a questionnaire of ocular symptoms decreased in both those who had cataract surgery and those who did not have surgery. There were no significant changes in SIT and corneal staining between VTP surgery group and the VTP non-surgery group. LLT values were stable for the 3-month follow-up time. The authors reported a significant difference in TBUT in the surgical group when comparing the eye that received VTP to the eye that didn't receive VTP at week 1 and 1-month exams (4.47 ± 2.77 vs 3.44 ± 2.23 and 4.72 ± 2.78 vs 3.44 ± 2.24 respectively). There was an increase seen in MGYLS from baseline to the 1-week visit in the VTP surgery group. There continued to be an increase in meibomian gland function at 3 months, but no difference was seen in the VTP non-surgery group. The authors report improvement in MGYLS after using VTP in both the surgery group and non-surgery group but acknowledge limitations to the study including no relief of subjective symptoms by the participants who underwent cataract surgery and improvement of symptoms in those who did not have surgery. The authors also note the SPEED questionnaire was not good at differentiating symptomatic and asymptomatic participants and recommend larger multicenter studies to confirm the results. There is also lack of comparison of automated VTP treatment to a manual process.

Another study reported on the use of automated VTP before cataract surgery. In this prospective, randomized controlled trial, Park and colleagues (2021) investigated the use of preoperative VTP on meibomian gland dysfunction in subjects prior to cataract surgery. Outcomes were measured by TBUT, Oxford corneal staining score, and LLT. OSDI and Dry Eye Questionnaires (DEQ) were also assessed. The authors also reported on meibomian gland atrophy, degree of gland expressibility, and quality of gland secretions. Participants were followed for 3 months. Analysis included 60 participants in the VTP treatment group and 48 participants in the control group (those who did not receive VTP prior to cataract surgery). In the control group, the authors report a decrease in meibomian gland expressibility, worsened quality of meibomian gland secretions, decreased LLT, and worsened corneal staining. The VTP treatment group showed improved patency of meibomian glands, improved meibum quality, increased TBUT, and reduced corneal staining. OSDI and DEQ questionnaires reported an improvement in subjective outcomes.

In a 2023 prospective interventional randomized controlled open-label clinical trial, Mencucci and colleagues reported the results of the effect of a single LipiFlow VTP treatment done prior to cataract surgery in reducing signs and symptoms of postoperative dry eye disease in those affected by mild-moderate meibomian gland dysfunction in comparison to a 1-month preoperative treatment with warm compresses. In the treatment group, 23 participants received a single VTP treatment 5 weeks before surgery and the control group (23 participants) received warm compresses and eyelid massages twice a day postoperatively for 1 month. Evaluations were conducted at baseline, 5 weeks preoperatively, 1 week postoperatively, and 1 month postoperatively. Efficacy was measured by SPEED questionnaire, TMH, NI-BUT, corneal fluorescein, staining, Schirmer I test and slitlamp. There were no adverse events reported during treatment or follow-up. In the treatment group, improvements were noted in the noninvasive break-up time, SPEED questionnaire, and meibomian gland functionality parameters. In the control group, there were no significant changes from baseline to 1 week postoperatively, but there were noted to be small improvements in the NI-BUT, SPEED questionnaire and meibomian gland functionality parameters. In the control group, between 1 week postoperatively and 1 month postoperatively, the scores worsened. Although scores improved with use of VTP, the limitations to this study include lack of monitoring of compliance with warm compresses and eyelid massages and short follow-up period (1 month postoperatively). Further studies with longer follow-up and larger sample sizes are necessary.

While some studies suggest that automated pulse pressure-heat devices appear to be a promising treatment for meibomian gland dysfunction, published literature has not shown how use of automated devices improves overall net health outcome.

Background/Overview

The meibomian glands are oil-secreting glands located within the eyelids. They are located in both the upper and lower eyelids. The ducts for the glands are located along the margin of the eyelid. They discharge an oily secretion known as sebum which lubricates the eyelids. The glands release the oil into tear film. The released oil helps to prevent the water in tears from evaporating. This helps to prevent dry eyes from occurring. If the oil becomes too thick, it can lead to a blockage of the duct which takes the oil from the gland to the tear film. The oil will continue to be made and this can lead to swelling and filling of the gland. A severe blockage can lead to enlarged glands or infection. Lack of oil in the tear film can also lead to dry eyes. An infection may require antibiotics. Conventional treatment includes unclogging the glands which are blocked. This can be accomplished by applying heat (such as a warm compress) to the eyelid and finger massage.

The U.S. Food and Drug Administration (FDA) has granted 510(k) marketing clearance to several devices for use in the application of localized heat and pressure therapy to the eyelids for chronic cystic conditions of the eyelids, including meibomian gland dysfunction. The LipiFlow system is an automated office-based device that allows heat to be applied to the palpebral surfaces of the upper and

lower eyelids directly over the meibomian glands, while simultaneously applying graded pulsatile pressure to the outer eyelid surfaces, thereby expressing the meibomian glands. The LipiView Ocular Surface Interferometer frequently used with the LipiFlow system, creates images to measure the tear film lipid layer. Listing LipiFlow as the predicate device, the iLux System® (MyAlcon, Fort Worth, TX) uses localized heat and pressure therapy for those with chronic diseases of the eyelid. Also listing LipiFlow as the predicate device, the TearCare® System by Sight Sciences, Inc. (Menlo Park, CA), an eyelid thermal pulsation system, uses localized heat therapy and a disposable device which performs manual expression of the meibomian glands. The device is intended to treat evaporative dry eye disease due to meibomian gland dysfunction.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

0207T	Evacuation of meibomian glands, automated, using heat and intermittent pressure, unilateral
0330T	Tear film imaging, unilateral or bilateral, with interpretation and report
0563T	Evacuation of meibomian glands, using heat delivered through wearable, open-eye eyelid treatment devices and manual gland expression, bilateral

ICD-10 Diagnosis

All diagnoses

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Websites for Additional Information

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale and References sections.
Reviewed	08/11/2022	MPTAC review. Updated Description/Scope, Rationale, Background/Overview, References, and Index sections.
Reviewed	08/12/2021	MPTAC review. Updated Rationale and References sections.
Reviewed	08/13/2020	MPTAC review. Updated Index. Updated Coding section; added 0563T.
Reviewed	08/22/2019	MPTAC review. Updated Rationale and References sections.
Reviewed	09/13/2018	MPTAC review. Updated References and Index sections.
Reviewed	11/02/2017	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Rationale section.
Reviewed	11/03/2016	MPTAC review. Updated the Rationale and References sections.
Revised	11/05/2015	MPTAC review. Addition of tear film imaging to Investigational and Not Medically Necessary Statement. Updated Description, Background/Overview and Coding sections. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. Updated Rationale and References sections.
Reviewed	11/14/2013	MPTAC review.
Reviewed	11/08/2012	MPTAC review. Updated Rationale, Background/Overview and References.
Reviewed	11/17/2011	MPTAC review. Updated Rationale, References and Index.
Reviewed	11/18/2010	MPTAC review. Updated Rationale and References.
New	11/19/2009	MPTAC review. Initial document development.
