

Department:	Pharmacy Management	Original Approval:	01/20/2016
Policy #:	PM132	Last Approval:	06/14/2018
Title:	Trastuzumab (Herceptin®)		
Approved By:	UM Committee		

REQUIRED CLINICAL DOCUMENTATION FOR REVIEW

Documentation required to determine medical necessity for Trastuzumab (Herceptin): History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service: -Diagnosis - Medication list (current and past) to include start and end dates of all chemotherapy regimens -Prescribed by or in consultation with an oncologist -Labs/diagnostics as indicated -Dosing and duration requested -Weight.

BACKGROUND

Herceptin is indicated for adjuvant treatment of human epidermal growth factor receptor 2 (HER2) overexpressing node positive or node negative (estrogen receptor [ER]/progesterone receptor [PR] negative or with one high risk feature) breast cancer 1) as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel; 2) with docetaxel and carboplatin; or 3) as a single agent following multi-modality anthracycline-based therapy.¹ Herceptin is also indicated for the treatment of HER2-overexpressing metastatic breast cancer, either in combination with paclitaxel for first-line treatment or as a single agent in patients who have received one or more chemotherapy regimens. In addition, Herceptin is indicated, in combination with cisplatin and capecitabine or 5-fluorouracil (5-FU), for the treatment of patients with HER2-overexpressing metastatic gastric or gastroesophageal (GE) junction adenocarcinoma, who have not received prior treatment for metastatic disease. For all indications, patients must be selected for therapy based on an FDA-approved companion diagnostic for Herceptin. Tests are specific for breast cancer or gastric cancer. Herceptin is a humanized monoclonal antibody that selectively binds with high affinity to the extracellular domain of the HER2 protein. The HER2 proto-oncogene encodes a transmembrane receptor protein which is structurally related to the epidermal growth factor receptor. Herceptin has been shown, in both *in vitro* assays and in animals, to inhibit the proliferation of human tumor cells that overexpress HER2.

Herceptin is available as lyophilized powder in a single-dose vial containing 150 mg per vial and in multi-use vials containing 420 mg per vial (latter will be discontinued).¹ Herceptin should be reconstituted to a 21 mg/mL solution, which should be diluted. Dilute reconstituted Herceptin solution using 250 mL of 0.9% Sodium Chloride Injection (do not use Dextrose 5% solution). The diluted solution is infused intravenously over 30 to 90 minutes. Herceptin should not be administered as an intravenous push or bolus.

DEFINITIONS

None.

INDICATIONS/CRITERIA

Medicaid Members	<i>Continue to criteria for approval below.</i>
Medicare Members	<i>Step-utilization of Part D drugs not required.</i>

Coverage of Herceptin is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. Breast Cancer.

Criteria. *The patient must meet the following criteria (A AND B):*

- A) Herceptin is prescribed by or in consultation with an oncologist; AND
- B) Patient meets ONE of the following criteria (i or ii):
 - i. Herceptin is being used for preoperative/adjuvant therapy and both of the following criteria are met (a and b):
 - a) Patient has HER2-positive disease; AND
 - b) Herceptin will be given as part of a taxane-containing regimen (e.g., paclitaxel or docetaxel); OR
 - ii. Herceptin is being used for recurrent or metastatic HER2-positive disease.

Herceptin is indicated for adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer 1) as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel; 2) with docetaxel and carboplatin; or 3) as a single agent following multi-modality anthracycline- (e.g., daunorubicin, doxorubicin, epirubicin, idarubicin) based therapy.¹ Herceptin is also indicated in combination with paclitaxel for first-line treatment of HER2 overexpressing metastatic breast cancer, and as a single agent for treatment of HER2 overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease.

The National Comprehensive Cancer Network (NCCN) breast cancer guidelines (version 2.2017) indicate that for *preoperative/adjuvant treatment* of HER2-positive breast cancer (all regimens category 2A), the preferred Herceptin-containing regimens include: doxorubicin/cyclophosphamide (AC) regimen followed by paclitaxel (T) plus concurrent Herceptin with or without Perjeta® (pertuzumab intravenous injection); or docetaxel/carboplatin/Herceptin (TCH) regimen with or without Perjeta.² Other Herceptin-containing preoperative/adjuvant regimens include: AC followed by docetaxel plus Herceptin with or without Perjeta; docetaxel/cyclophosphamide/Herceptin; 5-FU/epirubicin/cyclophosphamide (FEC) followed by docetaxel (or paclitaxel) plus Herceptin plus Perjeta; paclitaxel/Herceptin; or Herceptin plus Perjeta plus docetaxel (or paclitaxel) followed by FEC. Patients with HER2-positive tumors should be treated with preoperative systemic therapy including Herceptin for at least 9 weeks of preoperative therapy. A Perjeta-containing regimen may be given preoperatively in certain patients with HER2-positive early stage breast cancer. Herceptin may be used in combination with an aromatase inhibitor for recurrent or Stage IV ER-positive, HER2-positive disease in post-menopausal women or in men with

breast cancer. The preferred first-line agents for HER2-positive *recurrent or metastatic disease* (either hormone receptor-negative or hormone receptor-positive and refractory to endocrine therapy) include: Perjeta plus Herceptin plus docetaxel (category 1) or paclitaxel (category 2A). The guidelines also note that in the metastatic setting, patients previously treated with chemotherapy plus Herceptin without Perjeta may be considered for one line of therapy including both Herceptin plus Perjeta in combination with or without cytotoxic therapy (such as vinorelbine or a taxane). Other regimens for HER2-positive recurrent or metastatic disease include Herceptin plus paclitaxel with or without carboplatin; Kadcyla® (ado-trastuzumab emtansine intravenous injection) alone; or Herceptin plus one of the following drugs: docetaxel, vinorelbine, or capecitabine. The preferred agents for *Herceptin-exposed HER2-positive recurrent or metastatic disease* include Tykerb® (lapatinib tablets) plus capecitabine; Herceptin plus capecitabine; Herceptin plus Tykerb (without cytotoxic therapy); or Herceptin plus other chemotherapy agents (i.e., carboplatin, cisplatin, cyclophosphamide, eribulin, gemcitabine, Ixempra® (ixabepilone intravenous injection), Abraxane® [paclitaxel albumin-bound for injectable suspension], paclitaxel, capecitabine, docetaxel, vinorelbine). Several trials have shown benefit of continuing Herceptin therapy after disease progression on a Herceptin-containing regimen. However, the guidelines state that the optimal duration of Herceptin in patients with long-term control of disease is unknown. However 1 year of therapy with Herceptin is recommended.

In the Phase III Adjuvant Lapatinib and/or Trastuzumab Treatment Optimization (ALTTO) trial, 8,381 patients with HER2-positive *early breast cancer* were randomized to 1 year of adjuvant therapy with Herceptin, Tykerb, the sequence of Herceptin to Tykerb (H → T), or the combination of Herceptin and Tykerb.³ The Tykerb arm was closed early after the first interim analysis because the likelihood of showing non-inferiority to Herceptin was unlikely, and patients receiving Tykerb had a worse disease-free survival (DFS) than patients treated with Herceptin alone. In the intent-to-treat population there was a 16% reduction in the hazard of a DFS with Herceptin plus Tykerb compared with Herceptin, but this was not statistically significant and of minor clinical significance considering the additional toxicity with the combination. The authors concluded that 1 year of adjuvant Herceptin is the standard of care.

Breast cancer tumors are classified as HER2-positive if they demonstrate HER2 gene amplification by an *in situ* hybridization (ISH) method or are scored as 3+ by an immunohistochemistry (IHC) method.^{2,4} Samples scored as 2+ by the IHC method are designated as equivocal (borderline) and should be subjected to reflex testing by an ISH method to assign HER2 status. Similarly, samples with equivocal results by an ISH assay must be confirmed by counting additional cells or repeating the ISH assay. If the results continue to be equivocal, then reflex testing with IHC is recommended to assign HER2 status. To receive treatment with Herceptin, patients must be selected based on HER2 protein overexpression or HER2 gene amplification in tumor specimens.¹ Assessment of HER2 protein overexpression or HER2 gene amplification should be performed using FDA-approved tests specific for breast cancers by laboratories with demonstrated proficiency. Treatment guidelines for breast cancer indicate that patients with tumors IHC 0 or 1+ for HER2 or ISH not amplified (i.e., HER2-negative) have very low rates of HER2-targeted response, and therapy with Herceptin is not warranted.^{2,4} Treatment guidelines indicate that HER2-tumor status should be determined for all newly diagnosed invasive breast cancers and for first recurrences of breast cancer whenever possible if previously unknown or negative.

Dosing in Breast Cancer. Dosing must meet ONE of the following (A, B OR C):¹⁻²

PM132_CCC_Trastuzumab (Herceptin)

3 of 9

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- A) 4 mg per kg intravenous infusion followed by 2 mg per kg intravenous infusion weekly; OR
- B) 8 mg per kg intravenous infusion followed by 6 mg per kg intravenous infusion every 3 weeks;
OR
- C) 4 mg per kg intravenous infusion followed by 2 mg per kg intravenous infusion weekly during chemotherapy, followed by 6 mg per kg intravenous infusion every 3 weeks.

The approved dosing of Herceptin as adjuvant treatment of breast cancer is given for a total of 52 weeks according to one of the following doses and schedules.¹ When given during and following paclitaxel, docetaxel, or docetaxel/carboplatin, the initial Herceptin dose is 4 mg/kg as an intravenous infusion over 90 minutes and then 2 mg/kg over 30 minutes weekly during chemotherapy for the first 12 weeks (paclitaxel or docetaxel) or 18 weeks (docetaxel/carboplatin). One week following the last weekly dose of Herceptin, Herceptin 6 mg/kg is given as an intravenous infusion over 30 to 90 minutes every 3 weeks. A second adjuvant treatment regimen is Herceptin as a single agent within 3 weeks following completing multi-modality, anthracycline-based chemotherapy regimens: the initial dose of Herceptin is 8 mg/kg as an intravenous infusion over 90 minutes and subsequent doses are 6 mg/kg intravenous infusion over 30 to 90 minutes every 3 weeks. Extending adjuvant treatment beyond 1 year is not recommended. The approved dosing for metastatic breast cancer is Herceptin (alone or in combination with paclitaxel) at an initial dose of 4 mg/kg given over 90 minutes followed by weekly doses of 2 mg/kg over 30 minutes until disease progression. Many dosing schedules for Herceptin are included in the NCCN guidelines.² Preoperative therapy is 9 weeks of treatment before surgery with assessment of tumor response during delivery of therapy. Patients with operable breast cancer experiencing progression of disease during preoperative systemic therapy should be taken promptly to surgery. Alternate dosing will be assessed individually on a case-by-case basis.

Permanently discontinue Herceptin for severe or life-threatening infusion-related reactions, or for a persistent (more than 8 weeks) left ventricular ejection fraction (LVEF) decline or for suspension of Herceptin dosing on more than three occasions for cardiomyopathy.

Note: Dose modifications are recommended for the management of infusion reactions and cardiomyopathy, and are determined by the prescribing physician. See the prescribing information for more detail.

Initial Approval/Extended Approval.

- A) Preoperative/adjuvant therapy:
 - i. Initial Approval: Approve 12 months of therapy.
 - ii. Extended Approval: Approve 12 months of therapy.
- B) Recurrent or metastatic disease.
 - i. Initial Approval: Initial approval is for 6 months of therapy.
 - ii. Extended Approval: Approve at additional 6 month intervals, as determined by the prescribing physician.

Duration of therapy in Breast Cancer.

- A) For preoperative/adjuvant treatment: up to 52 weeks.
- B) For metastatic treatment: indefinite.

Labs/Diagnostics. Detection of HER2 protein overexpression or gene amplification is necessary for selection of patients appropriate for Herceptin therapy. See criteria above.

2. Gastric or Gastroesophageal (GE) Junction Cancer.

Criteria. *The patient must meet the following criteria (A, B, C, AND D):*

- A) Herceptin is prescribed by or in consultation with an oncologist; AND
- B) Patient has HER2-positive locally advanced or metastatic disease; AND
- C) Herceptin will be used in combination with cisplatin or oxaliplatin AND a fluoropyrimidine (capecitabine or 5-fluorouracil [5-FU]); AND
- D) Patient has not received prior treatment for metastatic disease.

Herceptin is indicated, in combination with cisplatin and capecitabine or 5-FU, for the treatment of patients with HER2-overexpressing metastatic gastric or GE junction adenocarcinoma, who have not received prior treatment for metastatic disease.¹ In the pivotal, open-label, Phase III study (Trastuzumab for Gastric Cancer [ToGA] study), eligible patients had inoperable locally advanced, recurrent, or metastatic adenocarcinoma of the stomach or GE junction with overexpression of HER2 (i.e., HER2-positive).⁵ Patients (n = 594) were randomized to treatment with chemotherapy that included capecitabine plus cisplatin or 5-FU plus cisplatin given every 3 weeks for 6 cycles or to chemotherapy in combination with Herceptin. Patients continued on therapy with Herceptin until disease progression, unacceptable toxicity, or withdrawal of consent. **Results.** Median overall survival (OS) was 13.8 months with Herceptin plus chemotherapy (95% confidence interval [CI]: 12, 16) and 11.1 months with chemotherapy alone (95% CI: 10, 13) [hazard ratio (HR) 0.74; 95% CI: 0.60, 0.91; P = 0.0046]. In a post hoc subgroup analysis of patients who received Herceptin plus chemotherapy, median OS was 16.0 months (95% CI: 15, 19) in patients with high expression of HER2 protein vs. 11.8 months (95% CI: 10, 13) in patients with low expression of HER2 protein. The HR for patient whose tumors had high HER2 expression was 0.65 (95% CI: 0.51, 0.83). In one multicenter Phase II trial, patients with HER2-positive advanced gastric cancer (n = 55) were given Herceptin in combination with capecitabine and oxaliplatin.⁶ **Results.** The objective response rate was 68% (95% CI: 54%, 80%). The disease control rate defined as the proportion of patients demonstrating complete responses, partial responses, or stable disease was 89% (95% CI: 78%, 95%). After a median follow-up period of 13.8 months (range, 6.1 to 23.9), the median PFS was 9.8 months (95% CI: 7.0, 12.6) and OS was 21.0 months (95% CI: 6.4, 35.7).

The NCCN clinical practice guidelines on gastric cancer (version 1.2017) and on esophageal and GE esophagogastric junction cancers (version 1.2017) state that for metastatic or locally advanced disease (where local therapy is not indicated) Herceptin should be added to first-line systemic chemotherapy for HER2-overexpressing adenocarcinoma in patients with Karnofsky performance score \geq 60% or Eastern Cooperative Oncology Group (ECOG) performance score \leq 2.⁷⁻⁸ The recommended regimens for metastatic or locally advanced HER2-positive gastric, esophageal, or esophagogastric junction adenocarcinoma are Herceptin in combination with cisplatin and a fluoropyrimidine (5-FU or capecitabine) [category 1] or Herceptin in combination with other chemotherapy agents (category 2B)

[various regimens based on individual patient variability]. Herceptin is not recommended for use in combination with anthracyclines.

To receive treatment with Herceptin, patients must be selected based on HER2 protein overexpression or HER2 gene amplification in tumor specimens.¹ Assessment of HER2 protein overexpression or HER2 gene amplification should be performed using FDA-approved tests specific for gastric cancers by laboratories with demonstrated proficiency. The NCCN guidelines recommend that patients with inoperable locally advanced, recurrent or metastatic adenocarcinoma of the stomach or esophagogastric junction who are being considered for Herceptin therapy be assessed for tumor HER2 overexpression using IHC and fluorescence *in situ* hybridization (FISH) or other *in situ* hybridization method.^{7,10} Tumors that show 2+ expression of HER2 by IHC should be also examined by FISH or other *in situ* hybridization method. Cases with 3+ overexpression by IHC or FISH positive are considered positive. The NCCN guidelines note that the most important clinical application of HER2 status in patients with gastric cancer concerns the management of patients with advanced or metastatic disease.⁷ The scoring system for breast cancer differs from that used for gastric or GE junction cancer.⁷⁻⁸ In a post-hoc subgroup analysis of the ToGA trial, the addition of Herceptin to chemotherapy improved OS in patients whose tumors were IHC 2+ and FISH positive or IHC 3+ when compared to patients whose tumors were IHC 0 or 1+ and FISH positive.^{5,7-8}

Dosing in Metastatic Gastric or Gastroesophagel (GE) Junction Cancer. Dosing must meet the following (A OR B):^{1,7-8}

- A) 8 mg per kg intravenous infusion followed by 6 mg per kg intravenous infusion every 3 weeks;^{1,5,7-8} OR
- B) 6 mg per kg intravenous infusion followed by 4 mg per kg intravenous infusion every 2 weeks.⁷⁻⁸

The approved dose of Herceptin given with chemotherapy in metastatic gastric cancer is an initial dose of 8 mg/kg as a 90-minute infusion that is followed by subsequent doses of 6 mg/kg given over 30 to 90 minutes every 3 weeks until progression.¹ The NCCN guidelines recommend either Herceptin 8 mg/kg on day 1 of Cycle 1 and then 6 mg/kg every 21 days or Herceptin 6 mg/kg on day 1 of Cycle 1 and then 4 mg/kg every 14 days for first-line or second-line therapy (in combination with chemotherapy) for metastatic or locally advanced gastric, esophageal, or GE junction cancer.⁷⁻⁸

Permanently discontinue Herceptin for severe or life-threatening infusion-related reactions, or for a persistent (more than 8 weeks) LVEF decline or for suspension of Herceptin dosing on more than three occasions for cardiomyopathy.¹

Note: Dose modifications are recommended for the management of infusion reactions and cardiomyopathy, and are determined by the prescribing physician. See the prescribing information for more detail.

Initial Approval/Extended Approval.

- A) Initial Approval: Initial approval is for 6 months of therapy.
- B) Extended Approval: Approve at additional 6-month intervals if the patient does not have disease progression, as determined by the prescribing physician.

Duration of Therapy in Gastric or Gastroesophageal (GE) Junction Cancer. Indefinite if the patient does not have disease progression.

Labs/Diagnostics. Detection of HER2 protein overexpression or gene amplification is necessary for selection of patients appropriate for Herceptin therapy. See criteria above.

Other Uses with Supportive Evidence

3. Patient has been Started on Herceptin.

Criteria. *The patient must meet the following criteria (A AND B):*

- A)** The patient has HER2-positive breast, gastric, or gastroesophageal (GE) junction cancer; AND
- B)** The patient meets the conditions for coverage required for **Dosing, Extended Approval, Duration of Therapy,** and **Labs/Diagnostics** for an approved use in this *Herceptin Utilization Review* policy.

4. Other Cancer Indications. Forward to the Medical Director for review on a case-by-case basis. Other indications supported in the *NCCN Compendium*⁹ include: leptomeningeal metastases from breast cancer (category 2A) [intrathecal route] and non-small cell lung cancer (category 2B).

Waste Management for All Indications.

- Weight-based dosing is used; the dose should be calculated and the number of vials needed assessed.

Conditions Not Recommended for Approval

Herceptin has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

SPECIAL CONSIDERATIONS

None.

LIMITATIONS/EXCLUSIONS

Please refer to a product line's certificate of coverage for benefit limitations and exclusions for these services:

PRODUCT LINE	LINK TO CERTIFICATE OF COVERAGE
MEDICARE ADVANTAGE	http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides
WASHINGTON APPLE HEALTH	http://chpw.org/our-plans/apple-health/
INTEGRATED MANAGED CARE	http://chpw.org/our-plans/apple-health/

Citations & References

References
<ol style="list-style-type: none"> 1. Herceptin® for injection for intravenous use [prescribing information]. South San Francisco, CA: Genentech, Inc.; April 2017. 2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (Version 2.2017 – April 6, 2017). © 2017 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 19, 2017. 3. Piccart-Gebhart M, Holmes E, Baselga J, et al. Adjuvant lapatinib and trastuzumab for early human epidermal growth factor receptor 2-positive breast cancer: results from the randomized phase III adjuvant lapatinib and/or trastuzumab treatment optimization trial. <i>J Clin Oncol</i>. 2016;34:1034-1042. 4. Wolff AC, Hammond EH, Hicks DG, et al. Recommendations for human epidermal growth factor receptor 2 testing in breast cancer: American Society of Clinical Oncology/College of American Pathologists clinical practice guideline update. <i>J Clin Oncol</i>. 2013;31:3997-4013. 5. Bang YJ, Van Cutsem E, Feyereislova A, et al. Trastuzumab in combination with chemotherapy versus chemotherapy alone for treatment of HER2-positive advanced gastric or gastro-oesophageal junction cancer (ToGA): a phase 3, open-label, randomized controlled trial. <i>Lancet</i>. 2010;376:687-697. 6. Ryu MH, Yoo C, Kim JG, et al. Multicenter phase II study of trastuzumab in combination with capecitabine and oxaliplatin for advanced gastric cancer. <i>Eur J Cancer</i>. 2015;51:482-488. 7. The NCCN Gastric Clinical Practice Guidelines in Oncology (Version 1.2017 – March 21, 2017). © 2017 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 19, 2017. 8. The NCCN Esophageal and Esophagogastric Junction Cancers Clinical Practice Guidelines in Oncology (Version 1.2017 – March 21, 2017). © 2017 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 19, 2017. 9. The NCCN Drugs & Biologics Compendium. © 2016 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 19, 2017. . Search term: trastuzumab. 10. Bartley AN, Washington MK, Ventura CB, et al. HER2 testing and clinical decision making in gastroesophageal adenocarcinoma: Guideline from the College of American Pathologists, American Society for Clinical Pathology, and American Society of Clinical Oncology. <i>Arch Pathol Lab Med</i>. 2016;140(12):1345-1363. 11. Olson E, Mullins D. When standard therapy fails in breast cancer: current and



	<p>future options for HER2-positive disease. <i>J Clin Trials</i>. 2014;3:1000129.</p> <p>12. Giordano SH, Temin S, Kirshner JJ, et al; American Society of Clinical Oncology. Systemic therapy for patients with advanced human epidermal growth factor receptor 2-positive breast cancer: American Society of Clinical Oncology clinical practice guideline. <i>J Clin Oncol</i>. 2014;32:2078-2099.</p> <p>13. Dang C, Iyengar N, Datko F, et al. Phase II study of paclitaxel given once per week along with trastuzumab and pertuzumab in patients with human epidermal growth factor receptor 2-positive metastatic breast cancer. <i>J Clin Oncol</i>. 2015;33:442-447.</p> <p>14. Swain SM, Baselga J, Kim SB, et al; CLEOPATRA Study Group. Pertuzumab, trastuzumab, and docetaxel in HER2-positive metastatic breast cancer. <i>N Engl J Med</i>. 2015;372:724-734.</p>
CFR	
WAC	WAC 284-43-2050
RCW	
Contract Citation	<input checked="" type="checkbox"/> WAH <input checked="" type="checkbox"/> IMC <input checked="" type="checkbox"/> MA
Other Requirements	
NCQA Elements	

Revision History

Revision Date	Revision Description	Revision Made By
01/13/2016	New	Kelly Force; Yusuf Rashid, RPh
01/20/2016	Approval	MMLT
01/12/2017	No revisions	Fran McGaugh
01/13/2017	Approval	MMLT
07/24/2017	Criteria completely updated and revised	Michael Sporck, Pharmacy Intern Sophia Yun, PharmD
03/09/2018	Reassigned from UM to Pharmacy	Cindy Bush
05/23/2018	No revisions	Jennifer Farley, PharmD
06/14/2018	Approval	UM Committee