Pharmacy Management Drug Policy

SUBJECT: Step Therapy
POLICY NUMBER: PHARMACY-72
EFFECTIVE DATE: 10/11
LAST REVIEW DATE: 11/21/2024

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☐ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☐ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☐ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Step Therapy encourages use of safe, cost-effective medications within different therapeutic drug categories. The entry of new generics and cost-effective therapeutic alternatives has provided an opportunity to promote these therapies as first-line.

POLICY:

Step Therapy requires members try certain first-line options before other medications will be considered medically necessary for treatment of a specific condition. Step therapy requirements may apply to both brands and generics. Typically, first-line medications are classified as generics, but there are instances where brand name medications may be preferred.

Based upon our review and assessment of the peer-reviewed literature, these medications have been medically proven to be effective and therefore **medically necessary** for medical treatment if the request meets the following criteria:

ANTIBACTERIALS	
Drug	**Requirement**
Doryx, Doryx MPC	Coverage requires documentation of serious side effects or drug failure with immediate-release doxycycline **AND** immediate-release minocycline
Doxycycline hyclate DR	
Clindagel 75 mL	Coverage requires documentation of serious side effects or drug failure with generic clindamycin **AND** tretinoin
Clindamycin 1% Gel 75 mL (Oceanside & Solaris)	
Amzeeq	Coverage requires serious side effects or drug failure with TWO topical treatments for acne (erythromycin, clindamycin, tretinoin, adapalene, dapsone, tazarotene)
Zilxi 1.5%	Coverage requires serious side effects or drug failure with topical metronidazole and one additional topical antibiotic (such as clindamycin, erythromycin, azelaic acid).

ANTICOAGULANTS	
Drug	**Requirement**
Savaysa	Coverage requires documentation of serious side effects or drug failure with Xarelto or Eliquis

ANTIDEPRESSANTS	
Drug	**Requirement**
Emsam	Coverage requires documentation of serious side effects or drug failure with at least **ONE** of the following first line agents: escitalopram, fluoxetine, citalopram, sertraline, paroxetine, mirtazapine, bupropion or venlafaxine **immediate-release** tablets or venlafaxine extended-release **capsules**
Forfivo XL 450 mg	
Venlafaxine ER **Tablets**	Coverage requires documentation of serious side effects or drug failure with venlafaxine ER capsules, **however:** • Equal doses of venlafaxine HCL extended-release tablets are bioequivalent to venlafaxine ER capsules, but are not substitutable at the pharmacy level • A daily dose of 225 mg venlafaxine ER may be obtained by ordering venlafaxine ER 75 mg capsules, taken as 3 capsules once daily • A daily dose of 112.5 mg venlafaxine ER may be obtained by ordering venlafaxine ER 37.5 mg capsules, taken as 3 capsules once daily • The claims processing system will not read history for this edit therefore claims will not automatically pay, therefore a manual step therapy request must be made for coverage determination
Drizalma Sprinkle	Coverage requires serious side effects or drug failure with duloxetine

ANTIEMETICS	
Drug	**Requirement**
Anzemet	Coverage requires documentation of serious side effects or drug failure with ondansetron
Sancuso	Coverage requires documentation of serious side effects or drug failure with ondansetron **AND** granisetron

ANTIFUNGAL AGENTS	
Drug	**Requirement**
Ecoza Ertaczo Luzu Luliconazole Naftifine Xolegel Oxistat Lotion	Coverage requires documentation of serious side effects or drug failure with TWO of the following generic topical antifungals: ciclopirox, econazole, ketoconazole, nystatin
Naftin	Coverage requires documentation of serious side effects or drug failure with TWO of the following generic topical antifungals: ciclopirox, econazole, ketoconazole, nystatin, **AND** generic naftifine

ORAL ANTIFUNGAL AGENTS		
Drug	**Diagnosis**	**Requirement**
Brexafemme	Vulvovaginal candidiasis (VVC)	Coverage requires documentation of serious side-effects or drug failure of oral fluconazole

	Recurrent vulvovaginal candidiasis (RVVC)	Coverage requires documentation of serious side-effects or drug failure of a 6-month oral fluconazole treatment course

ANTIMIGRAINE AGENTS

Drug	Requirement
Onzetra Spray	Coverage requires documentation of serious side effects or drug failure with TWO generic triptans:(Almotriptan, Eletriptan, Frovatriptan, Naratriptan, Rizatriptan, Sumatriptan, Zolmitriptan)
Zomig Nasal Spray/Zolmitriptan Nasal Spray	
Tosymra	Coverage requires documentation of serious side effects or drug failure with generic sumatriptan nasal spray **AND** TWO generics oral triptans: (Almotriptan, Eletriptan, Frovatriptan, Naratriptan, Rizatriptan, Sumatriptan, Zolmitriptan)
Zembrace	Coverage requires documentation of serious side effects or drug failure with injectable sumatriptan

ANTIPSYCHOTICS

Drug	Diagnosis	Requirement
Caplyta	Schizophrenia	Coverage requires documentation of serious side effects or drug failure with TWO generic atypical antipsychotics
	Bipolar Depression	Coverage requires documentation of serious side effects or drug failure with TWO alternative therapies for bipolar depression
Fanapt	Schizophrenia	Coverage requires documentation of serious side effects or drug failure with TWO generic atypical antipsychotics
	Bipolar Disorder	
Latuda	Schizophrenia	Coverage requires documentation of serious side effects or drug failure with TWO generic atypical antipsychotics
	Bipolar Depression	Coverage requires documentation of serious side effects or drug failure with TWO alternative therapies for bipolar depression
Rexulti	Schizophrenia	Coverage requires documentation of serious side effects or drug failure with TWO generic atypical antipsychotics
	Major Depressive Disorder	Coverage requires documentation of serious side effects or drug failure with TWO different antidepressants (with different mechanisms of action) used in combination **OR** ONE antidepressant in combination with ONE other augmentation therapy (such as atypical antipsychotic, lithium, buspirone)
	Agitation associated with Dementia due to Alzheimer disease	Requests for this diagnosis will be approved.
Secuado	Schizophrenia	Coverage requires documentation of serious side effects or drug failure with TWO generic atypical antipsychotics
Vraylar	Schizophrenia	

	Bipolar disorder	Coverage requires documentation of serious side effects or drug failure with TWO generic atypical antipsychotics
	Bipolar Depression	Coverage requires documentation of serious side effects or drug failure with TWO alternative therapies for bipolar depression
	Major Depressive Disorder	Coverage requires documentation of serious side effects or drug failure with TWO different antidepressants (with different mechanisms of action) used in combination **OR** ONE antidepressant in combination with ONE other augmentation therapy (such as atypical antipsychotic, lithium, buspirone)

ANTIVIRALS	
Drug	**Requirement**
Acyclovir 5% cream	Coverage requires documentation of serious side effects or drug failure with acyclovir 5% ointment.
Penciclovir 1% cream	
Xerese 5%-1% cream	
Zovirax 5% cream	Coverage requires documentation of serious side effects or drug failure with acyclovir 5% ointment **AND** generic acyclovir 5% cream
Denavir 1% cream	Coverage requires documentation of serious side effects or drug failure with acyclovir 5% ointment **AND** generic penciclovir 1% cream

BLOOD GLUCOSE REGULATORS (SELECT BENEFITS ONLY)	
Drug	**Requirement**
Admelog	Coverage requires documentation of serious side effects or drug failure with Humalog, Humalog Mix 75/25, or Insulin Lispro (Lilly authorized generic)
Apidra	
Fiasp	
Novolog, Novolog Mix 70/30, Insulin Aspart	
Novolin 70-30, Novolin N, Novolin R	Coverage requires documentation of serious side effects or drug failure with corresponding Humulin product (N, R, 70-30)
Nesina	Coverage requires documentation of serious side effects or drug failure with Januvia, Janumet, Tradjenta or Jentadueto
Alogliptin	
Kazano	
Alogliptin/metformin	
Oseni	
Alogliptin/pioglitazone	
Glumetza	Coverage requires documentation of serious side effects or drug failure with generic immediate-release metformin **AND** generic extended-release metformin (generic equivalent of Glucophage XR)
Fortamet	
Metformin ER (generics of Fortamet and Glumetza), Metformin HCl 625 mg	
Blood Glucose Meters and Test Strips	Coverage of any non-preferred blood glucose meter or test strip requires either: a previous trial and failure **OR** the inability to use any Abbott (Freestyle or Precision Xtra) or One Touch products
Qtern	Coverage requires documentation of serious side effects **OR** drug failure with Glyxambi and Steglujan.
Rezvoglar	Based on comparable indications, efficacy, safety profile, and equivalent strength of brand name Lantus, insulin glargine, and insulin glargine-yfgn, the member will be required to use brand name

	Lantus, insulin glargine, and insulin glargine-yfgn unless there is adequate justification as to why it will not work for you.
Invokamet, Invokamet Xr, Segluromet	Coverage requires documentation of serious side effects or drug failure with Xigduo XR AND Synjardy/Synjardy XR
Invokana, Steglatro	Coverage requires documentation of serious side effects or drug failure with Farxiga AND Jardiance
Dapagliflozin	Based on comparable indications, efficacy, safety profile, and equivalent strength of brand name Farxiga, the member will be required to use brand name Farxiga unless there is adequate justification as to why it will not work for you.
Dapagliflozin/Metformin	Based on comparable indications, efficacy, safety profile, and equivalent strength of brand name Xigduo, the member will be required to use brand name Xigduo unless there is adequate justification as to why it will not work for you.

CARDIOVASCULAR AGENTS

Drug	Requirement
Edarbi	Coverage requires documentation of serious side effects or drug failure with TWO of the following: losartan, irbesartan, valsartan
Edarbyclor	Coverage requires documentation of serious side effects or drug failure with TWO of the following: losartan/hctz, irbesartan/hctz, valsartan/hctz
Thalitone	Coverage requires documentation of serious side effects or drug failure with generic chlorthalidone.

CARDIOVASCULAR AGENTS, DYSLIPIDEMICS

Drug	Requirement
Livalo	Documentation of serious side effects or drug failure with TWO of the following generic statins: atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin
Pitavastatin Calcium	
Zypitamag	
Praluent	Coverage requires documentation of serious side effects or drug failure Repatha for those aged 10 years and older.

NEUROLOGICAL AGENTS

Drug	Requirement
Savella	Coverage requires documentation of serious side effects or drug failure with duloxetine
Adlarity	Coverage requires documentation of serious side effects or drug failure of donepezil, donepezil ODT, galantamine, **OR** rivastigmine
Xadago	Coverage requires documentation of serious side effects or drug failure with generic selegiline

DERMATOLOGICAL AGENTS

Drug	Requirement
Aczone 7.5%, Dapsone 7.5%	Coverage requires documentation of serious side effects or drug failure with a topical retinoid **AND** Dapsone 5%
Adapalene 0.1% Lotion, Soln, Swab	Coverage requires documentation of serious side effects or drug failure with adapalene cream or gel **AND** tretinoin cream or gel

Differin 0.1% Lotion	
Eucrisa Ointment	Coverage requires documentation of serious side effects or drug failure with ONE generic topical steroid (aclometasone, amcinonide, betamethasone, clobetasol, desonide, desoximetasone, diflorasone, fluocinolone, fluocinonide–E, fluticasone, halobetasol, hydrocortisone 2.5%, hydrocortisone valerate, hydrocortisone butyrate, mometasone, prednicarbate, triamcinolone) **OR** ONE of the following: tacrolimus ointment or pimecrolimus cream.
Noritate	Coverage requires documentation of serious side effects or drug failure with generic metronidazole cream, gel, or lotion
Zyclara 2.5% Cream Pump, Zyclara 3.75% Cream And Zyclara 3.75% Cream Pump	Coverage requires documentation of serious side effects or drug failure with imiquimod 5% cream
Imiquimod 3.75% Cream And Imiquimod 3.75% Cream Pump	

GASTROINTESTINAL AGENTS

Drug		Requirement
Amitiza	Chronic idiopathic constipation or IBS-C	Coverage requires documentation of serious side effects or drug failure with lubiprostone **AND <u>either</u>** Linzess **OR** Trulance for a diagnosis of chronic idiopathic constipation or irritable bowel syndrome with constipation.
	Opioid-induced constipation	Coverage requires documentation of drug failure or serious side effects with Movantik for a diagnosis of opioid induced constipation.
Motegrity		Coverage requires documentation of serious side effects or drug failure with Linzess OR Trulance for a diagnosis of chronic idiopathic constipation (CIC)
Relistor Tablet		Coverage requires documentation of serious side effects or drug failure with Movantik for a diagnosis of opioid-induced constipation
Symproic		
Ibsrela		Coverage requires documentation of serious side effects or drug failure with Linzess, lubiprostone, **AND** Trulance for a diagnosis of irritable bowel syndrome with constipation
Dexilant		Coverage requires documentation of serious side effects or drug failure with lansoprazole or omeprazole
Dexlansoprazole DR		
Omeprazole/Sodium Bicarbonate Packets		Coverage requires documentation of serious side effects or drug failure with THREE of the following: omeprazole, pantoprazole, lansoprazole, rabeprazole
Zegerid Packets		

Pheburane	Coverage requires documentation of serious side effects or drug failure with generic sodium phenylbutyrate

GENITOURINARY AGENTS; ANTISPASMODICS, URINARY

Drug	Requirement
Oxytrol	Coverage requires documentation of serious side effects or drug failure with TWO of the following: oxybutynin, oxybutynin ER, tolterodine, trospium, trospium XR **Exception:** Gelnique does not require step therapy for individuals 65 years of age or older
Gelnique	

HORMONAL AGENTS, STIMULANT/REPLACEMENT/MODIFYING (ADRENAL)

Drug	Requirement
Bryhali	Coverage requires documentation of a serious side effects or drug failure with TWO of the following generic topical steroids: aclometasone, amcinonide, betamethasone, clobetasol, desonide, desoximetasone, diflorasone, fluocinolone, fluocinonide–E, fluticasone, halobetasol (except foam), hydrocortisone 2.5%, hydrocortisone valerate, hydrocortisone butyrate (except lotion), mometasone, prednicarbate, triamcinolone
Cloderm, Clocortolone Pivalate	
Cordran (Cream, Lotion, Ointment)	
Desonide 0.05% Gel	
Halog, Halcinonide	
Halobetasol Propionate 0.05% Foam	
Impeklo	
Impoyz Spray	
Lexette	
Pandel	
Sernivo Lotion	
Ultravate Lotion	
Verdeso	

IMMUNOLOGICAL AGENTS

Drug	Requirement
Prograf Granules	Must have documentation of serious side effects or drug failure with generic tacrolimus capsules **Exception:** age less than 9 years old

MULTIPLE SCLEROSIS AGENTS

Drug	Requirement
Aubagio	Coverage requires documentation of serious side effects or drug failure with ONE of the following: Avonex, Copaxone (or Glatiramer), Glatopa, fingolimod, Mayzent, dimethyl fumarate, Plegridy, Rebif, teriflunomide, Kesimpta or Zeposia
Bafiertam	Coverage requires documentation of serious side effects or drug failure with TWO of the following agents: Avonex, Copaxone (or glatiramer), Glatopa, fingolimod, dimethyl fumarate, Mayzent, Plegridy, Rebif, teriflunomide, Kesimpta, or Zeposia.
Ponvory	
Vumerity	

OPHTHALMIC AGENTS

Drug		Requirement
Zerviate		Coverage requires documentation of serious side effects or drug failure with TWO of the following antihistamine eye drops: azelastine, olopatadine, epinastine
Xelpros	Vyzulta	Coverage requires documentation of serious side effects or drug failure with Lumigan **AND** either latanoprost or travoprost
Zioptan		

Iyuzeh	
Tafluprost	
Rhopressa, Rocklatan	Coverage requires documentation of serious side effects or drug failure with any covered prostaglandin analogue (such as bimatoprost, travoprost, latanoprost, Lumigan)
Restasis 0.05%	Coverage requires documentation of serious side effects or drug failure of cyclosporine 0.05% eye emulsion **AND** Xiidra 5% eye drops
Restasis Multidose 0.05%	
Atropine Sulfate/PF	Coverage requires documentation of serious side effects or drug failure of generic atropine 1% drops

PANCREATIC ENZYMES

Drug	Requirement
Pancreaze	Coverage requires documentation of serious side effects or drug failure with Creon and Zenpep
Pertzye	

RESPIRATORY TRACT/PULMONARY AGENTS

Drug	Requirement
Fluticasone-Salmeterol HFA	Based on comparable indications, efficacy, safety profile, and equivalent strength of brand name Advair HFA, the member will be required to use brand name Advair HFA unless there is adequate justification as to why it will not work for you.
Fluticasone-Vilanterol	Based on comparable indications, efficacy, safety profile, and equivalent strength of brand name Breo, the member will be required to use brand name Breo unless there is adequate justification as to why it will not work for you.
Tudorza Pressair	Coverage requires documentation of serious side effects or drug failure with ONE of the following: tiotropium bromide or Incruse.
Alvesco	Coverage requires documentation of serious side effects or drug failure with ONE of the following: Arnuity Ellipta, Asmanex, or Qvar Redihaler.
Pulmicort Flexhaler	
Armonair Digihaler	
AirDuo Respiclick	Coverage requires documentation of severe intolerance or therapeutic failure with generic fluticasone/salmeterol inhaler
AirDuo Digihaler	
Lonhala Magnair 25 mcg Starter	Coverage requires documentation of serious side effects or drug failure with any TWO of the following long-acting muscarinic receptor antagonists (LAMA) containing inhalers: Anoro Ellipta, Bevespi Aerosphere, Incruse Ellipta, Neohaler, tiotropium bromide Handihaler, Spiriva Respimat, Stiolto Respimat, or Utibron
Lonhala Magnair 25 mcg Refill	
Yupelri	
Duaklir Pressair	Coverage requires serious side effects or drug failure with at least TWO long-acting muscarinic receptor antagonist/long-acting beta agonist (LAMA/LABA) agents. Agents include: Anoro, Bevespi, Stiolto and Utibron.

SELECTIVE ESTROGEN RECEPTOR MODIFYING AGENTS

Drug	Requirement
Estring	Coverage requires documentation of serious side effects or drug failure with a topical vaginal estrogen product such as Premarin cream or estradiol vaginal cream.
Osphena	

SKELETAL MUSCLE RELAXANTS

Drug	Requirement
Norgesic Forte	Coverage requires documentation of serious side effects or drug failure with THREE of the following (generic) agents: baclofen, carisoprodol, chlorzoxazone, cyclobenzaprine, methocarbamol, metaxalone, orphenadrine, tizanidine
Orphengesic Forte	
Orphenadrine/ Aspirin/Caffeine	

SLEEP DISORDER AGENTS

Drug	Requirement
Edluar	Coverage requires documentation of serious side effects or drug failure with zolpidem
Zolpimist	
Belsomra, Dayvigo, Quviviq	Coverage requires documentation of serious side effects or drug failure with TWO of the following: zolpidem, eszopiclone, zaleplon

POLICY GUIDELINES:

1. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Coverage Exception Evaluation Policy for All Lines of Business Formularies policy for review guidelines.
2. Supportive documentation of previous drug use must be submitted for any criteria requiring trial of a preferred agent if the preferred drug is not found in claims history.
3. Approval for step therapy requirements may not bypass MAC penalty. Please see MAC penalty policy for detail of this benefit.
4. Utilization Management are contract dependent and coverage criteria may be dependent on the contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions.
5. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
   a. The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
   b. The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
   c. The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
   d. The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
   e. The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
   f. The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.

6. Initial approval will be granted for a period of 1 year.
   - Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition.
7. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit which support continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
8. In addition to the full prescribing information for each individual drug, the corresponding clinical guidelines (i.e., NCCN, DSM, etc.) are reviewed on an annual basis to determine the appropriateness of the medical necessity criteria that is applied.
9. *All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32)*

UPDATES:

Date	Revision
11/21/2024	P&T Committee Review / Approval
10/21/2024	Revised
09/23/2024	Revised
09/13/2024	Revised
08/13/2024	Revised
05/10/2024	Revised
04/09/2024	Revised
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12/15/2022	Revised
12/2/22	Revised

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11/3/22	Revised
10/3/22	Revised
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5/1/2022	Revised
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6/2020	Revised
5/2020	Revised
3/20	Revised
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10/19	Revised
8/19	Revised
7/19	Revised
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2/19	Revised
1/19	Revised
11/18	Revised
10/18	Revised

9/18	Revised
5/18	Revised
4/18	Revised
3/18	Revised
2/18	Revised
1/18	Revised- Both STEP Policies combined to one policy The Commercial Open step therapy and Exchange Closed/CHP policies have been merged. The policy has also been changed into a table format with headers that match the web formularies (derived from RxFlex).
12/17	Revised
11/2017	P&T Committee Approval
9/17	Revised
7/17	Revised
5/17	Revised
4/17	Revised
1/17	Revised
10/16	Revised
9/16	Revised
8/16	Revised
7/16	Revised
6/16	Revised
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1/16	Revised
12/15	Revised
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5/15	Revised
4/15	Revised
3/15	Revised
1/15	Revised
11/14	Revised
10/14	Revised
8/14	Revised
7/14	Revised
5/14	Revised
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