

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Vibegron (Gemtesa)

Notes:

- Quantity Limits: Yes
- ^ Adequate trial is defined as 12-week treatment duration
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Initiation (new start) criteria: Non-formulary **vibegron (Gemtesa)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Diagnosis of overactive bladder (including urinary urgency, urinary frequency, and urge incontinence) on the problem list
- Prescribed by Urology or Urogynecology
- Documented treatment failure, intolerance*, or contraindication to mirabegron
- Diagnosis of dementia or receiving medications indicated for dementia (e.g., acetylcholinesterase inhibitors or NMDA receptor antagonists)

-OR-

- If patient is less than 64 years old:
Documented treatment failure, intolerance*, or contraindication to at least two (2) anticholinergic agents (e.g., oxybutynin, trospium, or solifenacin)

-OR-

- If the patient is 64 years and older:
Documented treatment failure, intolerance*, or contraindication to at least two (2) anticholinergic agents (e.g., oxybutynin, trospium, or solifenacin) **-OR-**
- Already taking other anticholinergic drug(s) for any indication (see table below)

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Non-formulary **vibegron (Gemtesa)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Diagnosis of overactive bladder (including urinary urgency, urinary frequency, and urge incontinence) on the problem list
- Prescribed by Urology or Urogynecology
- Documented treatment failure, intolerance*, or contraindication to mirabegron

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- Diagnosis of dementia or receiving medications indicated for dementia (e.g., acetylcholinesterase inhibitors or NMDA receptor antagonists)

-OR-

- If patient is less than 64 years old:
Documented treatment failure, intolerance*, or contraindication to at least two (2) anticholinergic agents (e.g., oxybutynin, trospium, or solifenacin)

-OR-

- If the patient is 64 years and older:
Documented treatment failure, intolerance*, or contraindication to at least two (2) anticholinergic agents (e.g., oxybutynin, trospium, or solifenacin) **-OR-**
Already taking other anticholinergic drug(s) for any indication (see table below)

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary vibegron (Gemtesa) will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Diagnosis of overactive bladder (including urinary urgency, urinary frequency, and urge incontinence) on the problem list
- Prescribed by Urology or Urogynecology
- Documented treatment failure, intolerance*, or contraindication to mirabegron
- Diagnosis of dementia or receiving medications indicated for dementia (e.g., acetylcholinesterase inhibitor or NMDA receptor antagonists)

-OR-

- If patient is less than 64 years old:
Documented treatment failure, intolerance*, or contraindication to at least two (2) anticholinergic agents (e.g., oxybutynin, trospium, or solifenacin)

-OR-

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- If the patient is 64 years and older:
Documented treatment failure, intolerance*, or contraindication to at least two (2) anticholinergic agents (e.g., oxybutynin, trospium, or solifenacin) **-OR-**
- Already taking other anticholinergic drug(s) for any indication (see table below)

Continued use criteria (12 months after initiation): Non-formulary **vibegron (Gemtesa)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Patient continues to be under the care of Urology or Urogynecology
- Prescribing Urologist or Urogynecologist attests patient is receiving benefit from therapy

Continued use criteria for patients stable on the medication: Non-formulary **vibegron (Gemtesa)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Patient continues to be under the care of Urology or Urogynecology
- Prescribing Urologist or Urogynecologist attests patient is receiving benefit from therapy

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Drugs with Strong Anticholinergic Properties

Amitriptyline	Clomipramine	Disopyramide	Methscopolamine	Protriptyline
Amoxapine	Clozapine	Doxepin (>6 mg)	Nortriptyline	Pyrilamine
Atropine (excludes opht)	Cyclobenzaprine	Doxylamine	Olanzapine	Scopolamine (excludes opht)
Belladonna alkaloids	Cyproheptadine	Fesoterodine	Orphenadrine	Solifenacin
Benztropine	Darifenacin	Flavoxate	Oxybutynin	Thioridazine
Brompheniramine	Desipramine	Homatropine (excludes opht)	Paroxetine	Tolterodine
Carbinoxamine	Dexbrompheniramine	Hydroxyzine	Perphenazine	Trifluoperazine
Chlorpheniramine	Dexchlorpheniramine	Hyoscyamine	Prochlorperazine	Trihexyphenidyl
Chlorpromazine	Dicyclomine	Imipramine	Promethazine	Trimipramine
Clemastine	Dimenhydrinate	Loxapine	Promethazine	Triprolidine
Clidinium-chlordiazepoxide	Diphenhydramine (oral)	Meclizine	Propantheline	Trospium

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