

Clinical Policy: Aprepitant (Aponvie, Emend, Cinvanti), Fosaprepitant (Emend for injection, Focinvez)

Reference Number: CP.PMN.19

Effective Date: 11.01.06

Last Review Date: 08.24

Line of Business: HIM*, Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Aprepitant (Aponvie[™], Emend[®], Cinvanti[®]) and Fosaprepitant (Emend[®] for injection, Focinvez[®]) are substance P/neurokinin 1 (NK₁) receptor antagonists.

**For Health Insurance Marketplace (HIM), if request is through the pharmacy benefit, Aponvie, Emend, fosaprepitant (Emend for injection, Focinvez), and Cinvanti are non-formulary and should not be approved using these criteria; refer to the formulary exception policy, HIM.PA.103.*

FDA Approved Indication(s)

Aponvie, Emend, Cinvanti, and Focinvez are indicated:

- In combination with other antiemetic agents for adults (*Cinvanti*), patients 6 months of age and older (*Emend oral suspension and injection, Focinvez*), or 12 years of age and older (*Emend capsules*), for prevention of:
 - Acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin
 - Nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) (*Cinvanti and Emend oral suspension/capsules only*)
 - Delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) (*Emend injection, Focinvez, and Cinvanti only*).
- For prevention of postoperative nausea and vomiting (PONV) in adults (*generic aprepitant capsules and Aponvie only*)

Limitation(s) of use:

- Aponvie, Emend, Cinvanti, and Focinvez have not been studied for treatment of established nausea and vomiting.
- Chronic continuous administration of Emend oral suspension/capsules is not recommended.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Aponvie, Emend, Cinvanti, and Focinvez are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

- A. Prevention of Nausea and Vomiting Associated with Cancer Chemotherapy** (must meet all):

1. Request is for generic aprepitant capsules, Emend, Cinvanti, or Focinvez;
2. Prescribed for the prevention of chemotherapy-induced nausea/vomiting;
3. Member meets one of the following (a, b, or c):
 - a. Emend oral suspension, Emend for injection, or Focinvez: age \geq 6 months;
 - b. Emend capsules: age \geq 12 years;
 - c. Cinvanti: age \geq 18 years;
4. Member is scheduled to receive moderately to highly emetogenic cancer chemotherapy (*see Appendix D*);
5. Prescribed in combination with a serotonin (5-HT₃) receptor antagonist (*ondansetron is preferred*) and dexamethasone;
6. If request is for brand Emend, Focinvez, or Cinvanti, one of the following (a or b):
 - a. Member must use generic aprepitant or fosaprepitant, unless contraindicated or clinically significant adverse effects are experienced;
 - b. Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (*see Appendix E*);
7. Dose does not exceed one of the following (a, b, or c):
 - a. Emend oral suspension or capsules, both of the following (i and ii):
 - i. 125 mg on Day 1, followed by 80 mg on Days 2 and 3 per chemotherapy cycle;
 - ii. If age \geq 6 months and $<$ 12 years: 3 mg/kg on Day 1, followed by 2 mg/kg on Days 2 and 3 per chemotherapy cycle;
 - b. Emend for injection or Focinvez, one of the following (i or ii):
 - i. Single-dose regimen, all of the following (1, 2, and 3):
 - 1) 150 mg on Day 1;
 - 2) If age 2 years to $<$ 12 years: 4 mg/kg on Day 1;
 - 3) If age 6 months to $<$ 2 years: 5 mg/kg on Day 1
 - ii. 3-day regimen, both of the following (1 and 2):
 - 1) 115 mg on Day 1;
 - 2) If age 6 months to $<$ 12 years: 3 mg/kg on Day 1
 - c. Cinvanti, one of the following (i or ii):
 - i. Single-dose regimen: 130 mg on Day 1 for HEC and MEC;
 - ii. 3-day regimen: 100 mg on Day 1 for MEC.

Approval duration:

Medicaid – Projected duration of chemotherapy

HIM – Projected duration of chemotherapy (*refer to HIM.PA.103 for Emend, fosaprepitant (Emend for injection, Focinvez), and Cinvanti if pharmacy benefit*)

B. Prevention of Postoperative Nausea and Vomiting (must meet all):

1. Request is for generic aprepitant capsules or Aponvie;
2. Prescribed for the prevention of PONV;
3. Age \geq 18 years;
4. Member is scheduled to receive surgery;
5. Failure of a 5-HT₃ receptor antagonist (*ondansetron is preferred*) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;

6. Dose does not exceed one of the following (a or b):
 - a. Generic aprepitant capsules: 40 mg (1 capsule) once;
 - b. Aponvie: 32 mg (one vial) once.

Approval duration:

Medicaid – 3 days (one time dose)

HIM – 3 days (one time dose) (*refer to HIM.PA.103 for Aponvie if pharmacy benefit*)

C. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Prevention of Nausea and Vomiting Associated with Cancer Chemotherapy (must meet all):

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy;
3. Member continues to receive moderately to highly emetogenic cancer chemotherapy (*see Appendix D*);
4. Prescribed in combination with a 5-HT₃ receptor antagonist (*ondansetron is preferred*) and dexamethasone;
5. If request is for brand Emend, Focinvez, or Cinvanti, one of the following (a or b):
 - a. Member must use generic aprepitant or fosaprepitant, unless contraindicated or clinically significant adverse effects are experienced;
 - b. Request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings (*see Appendix E*);
6. If request is for a dose increase, new dose does not exceed one of the following (a, b, or c):
 - a. Emend oral suspension or capsules, both of the following (i and ii):

- i. 125 mg on Day 1, followed by 80 mg on Days 2 and 3 per chemotherapy cycle;
- ii. If age \geq 6 months and $<$ 12 years: 3 mg/kg on Day 1, followed by 2 mg/kg on Days 2 and 3 per chemotherapy cycle;
- b. Emend for injection or Focinvez, one of the following (i or ii):
 - i. Single-dose regimen, all of the following (1, 2, and 3):
 - 1) 150 mg on Day 1;
 - 2) If age 2 years to $<$ 12 years: 4 mg/kg on Day 1;
 - 3) If age 6 months to $<$ 2 years: 5 mg/kg on Day 1;
 - ii. 3-day regimen, both of the following (1 and 2):
 - 1) 115 mg on Day 1;
 - 2) If age 6 months to $<$ 12 years: 3 mg/kg on Day 1;
- c. Cinvanti, one of the following (i or ii):
 - i. Single-dose regimen: 130 mg on Day 1 for HEC and MEC;
 - ii. 3-day regimen: 100 mg on Day 1 for MEC.

Approval duration:

Medicaid – Projected duration of chemotherapy

HIM – Projected duration of chemotherapy (*refer to HIM.PA.103 for Emend, fosaprepitant (Emend for injection, Focinvez), and Cinvanti if pharmacy benefit*)

B. Prevention of Postoperative Nausea and Vomiting

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

C. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

5-HT ₃ : serotonin 5-hydroxytryptamine, type 3	MEC: moderately emetogenic cancer chemotherapy
ASCO: American Society of Clinical Oncology	NCCN: National Comprehensive Cancer Network
FDA: Food and Drug Administration	NK ₁ : neurokinin 1
HEC: highly emetogenic cancer chemotherapy	PONV: postoperative nausea and vomiting

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
5-HT₃ Serotonin Antagonists		
granisetron (Kytril [®])	Prevention of PONV* 0.35 to 3 mg (5 to 20 mcg/kg) IV at the end of surgery	20 mcg/kg/dose
ondansetron (Zofran [®] , Zofran [®] ODT)	Prevention of PONV 16 mg PO given 1 hour prior to anesthesia or 4 mg IM/IV as a single dose given 30 min before end of anesthesia	PO: 16 mg/dose IV: 4 mg/dose

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

**Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity, concurrent use with pimozide
- Boxed warning(s): none reported

Appendix D: American Society of Clinical Oncology (ASCO) and National Comprehensive Cancer Network (NCCN) Recommendations in Oncology

- Minimal emetic risk chemotherapy: No routine prophylaxis is recommended.
- Low emetic risk chemotherapy: Recommended options include dexamethasone (recommended by both ASCO and NCCN) or metoclopramide, or prochlorperazine, or a 5-HT₃ receptor antagonist (recommended by NCCN only). NK₁ receptor antagonists are not included in low risk antiemetic recommendations.
- Moderate emetic risk chemotherapy: 5-HT₃ receptor antagonists and dexamethasone may be used in combination and with or without NK₁ receptor antagonists. Olanzapine may also be used in combination with palonosetron and dexamethasone.
 - Examples of moderate emetic risk chemotherapy: bendamustine, carboplatin, clofarabine, cyclophosphamide ≤ 1,500 mg/m², cytarabine > 200 mg/m², daunorubicin, doxorubicin < 60 mg/m², epirubicin ≤ 90 mg/m², idarubicin, ifosfamide, irinotecan, oxaliplatin

- High emetic risk chemotherapy: NK₁ receptor antagonists are recommended for use in combination with 5-HT₃ receptor antagonists and dexamethasone. Olanzapine may also be used in combination with 5-HT₃ receptor antagonists, dexamethasone, and/or NK₁ receptor antagonists.
 - Examples of high emetic risk chemotherapy: carmustine, cisplatin, cyclophosphamide > 1,500 mg/m², dacarbazine, mechlorethamine, streptozocin, fam-trastuzumab deruxtecan-nxki
- Breakthrough emesis: Per NCCN, an agent from a different drug class is recommended to be added to the current antiemetic regimen. Drug classes include atypical antipsychotics (olanzapine), benzodiazepines (lorazepam), cannabinoids (dronabinol, nabilone), phenothiazines (prochlorperazine, promethazine), 5-HT₃ receptor antagonists (dolasetron, ondansetron, granisetron), steroids (dexamethasone), or haloperidol, metoclopramide, scopolamine. An NK₁ receptor antagonist may be added to the prophylaxis regimen of the next chemotherapy cycle if not previously included.

Appendix E: States with Regulations against Redirections in Stage IV or Metastatic Cancer

State	Step Therapy Prohibited?	Notes
FL	Yes	For stage 4 metastatic cancer and associated conditions.
GA	Yes	For stage 4 metastatic cancer. Redirection does not refer to review of medical necessity or clinical appropriateness.
IA	Yes	For standard of care stage 4 cancer drug use, supported by peer-reviewed, evidence-based literature, and approved by FDA.
LA	Yes	For stage 4 advanced, metastatic cancer or associated conditions. Exception if “clinically equivalent therapy, contains identical active ingredient(s), and proven to have same efficacy.
MS	Yes	<i>*Applies to HIM requests only*</i> For advanced metastatic cancer and associated conditions
NV	Yes	Stage 3 and stage 4 cancer patients for a prescription drug to treat the cancer or any symptom thereof of the covered person
OH	Yes	<i>*Applies to Commercial and HIM requests only*</i> For stage 4 metastatic cancer and associated conditions
OK	Yes	<i>*Applies to HIM requests only*</i> For advanced metastatic cancer and associated conditions
PA	Yes	For stage 4 advanced, metastatic cancer
TN	Yes	For advanced metastatic cancer and associated conditions
TX	Yes	For stage 4 advanced, metastatic cancer and associated conditions

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Aprepitant (Aponvie)	Prevention of postoperative nausea and vomiting	32 mg IV prior to induction of anesthesia	32 mg
Aprepitant (Cinvanti)	Prevention of chemotherapy-	<i>HEC or MEC (single-dose regimen):</i> 130 mg IV on Day 1	Single-dose: 130 mg/dose

Drug Name	Indication	Dosing Regimen	Maximum Dose
	induced nausea and vomiting	<i>MEC (3-day regimen):</i> 100 mg IV on Day 1	3-day regimen: 100 mg/dose
Aprepitant (Emend)	Prevention of chemotherapy-induced nausea and vomiting	<i>Capsules:</i> 125 mg PO on Day 1, then 80 mg PO on Days 2 and 3 of each chemotherapy cycle <i>Oral suspension:</i> 3 mg/kg PO on Day 1, then 2 mg/kg PO on Days 2 and 3	Per chemotherapy cycle: Day 1: 125 mg Days 2 and 3: 80 mg
	Prevention of postoperative nausea and vomiting	<i>Capsules:</i> 40 mg PO within 3 hours prior to induction of anesthesia	40 mg/dose
Fosaprepitant (Emend for injection)	Prevention of chemotherapy-induced nausea and vomiting	Adults: <u>HEC or MEC (single-dose):</u> 150 mg IV over 20 to 30 minutes on Day 1 Pediatric: <u>HEC or MEC (single-dose regimen):</u> <i>12 to 17 years:</i> 150 mg IV over 30 minutes <i>2 years to < 12 years:</i> 4 mg/kg IV over 60 minutes <i>6 months to < 2 years:</i> 5 mg/kg IV over 60 minutes <u>HEC or MEC (3-day regimen):</u> <i>12 to 17 years:</i> 115 mg IV over 30 minutes on day 1, followed by Emend capsules PO Days 2 and 3 <i>6 months to < 12 years:</i> 3 mg/kg IV over 60	Adult or pediatric single-dose: 150 mg/dose Pediatric, multi-day regimen: 115 mg/dose on Day 1

Drug Name	Indication	Dosing Regimen	Maximum Dose
		minutes on Day 1, followed by Emend for oral suspension on Days 2 and 3	
Fosaprepitant (Focinvez)	Prevention of chemotherapy-induced nausea and vomiting	<p>Adults: <u>HEC or MEC (single-dose):</u> 150 mg IV over 20 to 30 minutes on Day 1</p> <p>Pediatric: <u>HEC or MEC (single-dose regimen):</u> <i>12 to 17 years:</i> 150 mg IV over 30 minutes</p> <p><i>2 years to < 12 years:</i> 4 mg/kg IV over 60 minutes</p> <p><i>6 months to < 2 years:</i> 5 mg/kg IV over 60 minutes</p> <p><u>HEC or MEC (3-day regimen):</u> <i>12 to 17 years:</i> 115 mg IV over 30 minutes on Day 1, followed by Emend capsules PO Days 2 and 3</p> <p><i>6 months to < 12 years:</i> 3 mg/kg IV over 60 minutes on Day 1, followed by Emend for oral suspension on Days 2 and 3</p>	<p>Adult or pediatric single-dose: 150 mg/dose</p> <p>Pediatric, multi-day regimen: 115 mg/dose on Day 1</p>

VI. Product Availability

Drug Name	Availability
Aprepitant (Aponvie)	Single-dose vial, injectable emulsion: 32 mg/4.4 mL
Aprepitant (Cinvanti)	Single-dose vial, injectable emulsion: 130 mg/18 mL
Aprepitant (Emend)	Capsules: 40 mg, 80 mg, 125 mg

Drug Name	Availability
	Capsule therapy pack: 80 mg/125 mg Powder for oral suspension: 125 mg
Fosaprepitant (Emend for injection)	Single-dose vial for injection, powder for reconstitution: 150 mg
Fosaprepitant (Focinvez)	Single-dose vial for injection: 150 mg/50 mL

VII. References

1. Emend Prescribing Information. Whitehouse Station, NJ: Merck & Company, Inc.; November 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021549s030,207865s0031bl.pdf. Accessed May 9, 2024.
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8. National Comprehensive Cancer Network. Antiemesis Version 1.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Accessed May 20, 2024.
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Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J1453	Injection, fosaprepitant, 1 mg
J1456	Injection, fosaprepitant (Teva), not therapeutically equivalent to J1453, 1 mg
J0185	Injection, aprepitant, 1 mg
J8501	Aprepitant, oral, 5 mg
C9145	Injection, aprepitant, (Aponvie), 1 mg
J1434	Injection, fosaprepitant (Focinvez), 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2021 annual review: no significant changes; removed HIM-Medical Benefit; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	11.13.20	02.21
1Q 2022 annual review: added redirection to generic formulations; added HCPCS code for oral aprepitant; references reviewed and updated.	10.01.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section	09.20.22	
1Q 2023 annual review: RT4 added Aponvie to policy; updated FDA approved indications section to align with prescribing information for their respective products; for the prevention of chemotherapy-induced nausea/vomiting added requirement that request is for generic aprepitant capsules, Emend, or Cinvanti as these are the only products FDA-approved for this indication; references reviewed and updated. Updated HCPCS code [J1456].	01.23.23	02.23
Updated HCPCS code [C9145] for Aponvie.	01.24.23	
3Q 2023 annual review: added HCPCS code J3490 for unclassified drugs; for prevention of nausea and vomiting associated with cancer chemotherapy added allowance for bypassing redirection if state regulations do not allow step therapy in certain oncology settings with additional details in Appendix E; references reviewed and updated; updated Appendix E to include Oklahoma.	04.19.23	08.23
RT4: Focinvez added to policy; added Emend for injection to section V.	09.07.23	
Added HCPCS code [J1434] and removed HCPCS code [J3490]	02.20.24	
Updated Appendix E to include Mississippi.	06.05.24	
3Q 2024 annual review: no significant changes; references reviewed and updated.	05.09.24	08.24

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members,

and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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