MEDICAL POLICY UPDATE

FOR PROFESSIONAL AND FACILITY PROVIDERS

HIGHMARK.

August 2021

In This Issue

Policy

Language Updates, Criteria Updates and Futility Guidance Added to ECMO policy

NEWS FOR ALL PROVIDER TYPES

Highmark Blue Shield has revised criteria for G-44 Extracorporeal Membrane Oxygenation (ECMO)

Language has also been revised and determination of futility has been updated.

The revised policy will apply to professional providers and facility claims. The effective date is November 29, 2021.

Place of Service: Inpatient

Please refer to Medical Policy G-44 Extracorporeal Membrane Oxygenation, for additional information.

Criteria Revised for Assisted Reproductive Technology

Highmark Blue Shield has revised criteria for Assisted Reproductive Technology.

The following statement has been added to the In Vitro Fertilization policy position:

- In vitro fertilization (IVF) including cycles in which donor eggs, sperm, or embryos are used and including cycles where the embryo is transferred to a surrogate may be considered medically necessary.

The Gestational Carrier/Surrogate policy position has been revised to state the following:

- Services provided to a surrogate or gestational carrier may be a benefit exclusion.
- Payment for surrogate service fees for purposes of childbirth are considered not medically necessary.

This revised Medical Policy will apply to professional providers. The effective date is November 29, 2021.

Place of Service:

Please refer to Medical Policy U-5, Assisted Reproductive Technology, for additional information.

Coverage Guidelines Revised for Irinotecan (Camptosar)

Highmark Blue Shield has revised criteria for Irinotecan (Camptosar). The following has been updated:

Bone Cancer, Ewing Sarcoma is being updated to be used as Second-line therapy in combinations with temozolomide with or without vincristine.

Colon Cancer, Adenocarcinoma is being revised as followed:

- Subsequent therapy for progression of advanced or metastatic disease when:
  - Used as a single agent or in FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen with or without bevacizumab (preferred**), ziv-aflibercept, or ramucirumab if previously treated with oxaliplatin-based therapy without irinotecan or with therapy without irinotecan or oxaliplatin; **or**
  - Used in FOLFIRI regimen with cetuximab or panitumumab (KRAS/NRAS/BRAF wild-type only) if previously treated with oxaliplatin-based regimens without irinotecan; **or**
  - Used in combination with cetuximab or panitumumab (KRAS/NRAS/BRAF wild-type only) if previously treated with oxaliplatin and/or irinotecan; **or**

Colon Cancer, Adenocacinoma is being updated to remove

- Subsequent therapy for progression of advanced or metastatic disease when used in combination with vemurafenib and cetuximab or panitumumab (if BRAF V600E mutation positive) if previously treated with oxaliplatin and/or irinotecan and if not previously treated with cetuximab or panitumumab
- primary treatment for individuals with unresectable metachronous metastases and previous adjuvant FOLFOX or CapeOx within the past 12 months when used in combination with vemurafenib and cetuximab or panitumumab for BRAF V600E mutation positive tumors.

Lung Cancer, Small Cell (SCLC) is being updated to remove subsequent systemic therapy for individuals with performance status 0-2 when not used as original regimen and used in combination with cisplatin or carboplatin for primary progressive disease.

Ovarian Cancer-epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer is being updated to remove single agent therapy for persistent disease or recurrence when used in combination with cisplatin for clear cell carcinoma.

Rectal Cancer, Adenocarcinoma is being updated to remove the following:

- Primary treatment with FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin and irinotecan) regimen with cetuximab or panitumumab for synchronous liver only and/or lung only metastases (KRAS/NRAS/BRAF wild-type gene only) that are unresectable or medically inoperable; **or**
    - Used in FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen with or without bevacizumab or with or without cetuximab or panitumumab (KRAS/NRAS/BRAF wild-type gene only) or in FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen with or without bevacizumab as:
    - Primary treatment for synchronous liver only and/or lung only metastases that are unresectable or medically inoperable; **or**
    - As systemic therapy for synchronous liver only and/or lung only metastases that are unresectable or medically inoperable and remain unresectable (with no progression of primary tumor) after primary systemic therapy; **or**
    - As systemic therapy following short-course radiation therapy (RT) or chemo/RT for synchronous liver only and/or lung only metastases that are unresectable or medically inoperable and remain unresectable (with progression of primary tumor) after primary systemic therapy; **or**
    - Primary treatment for synchronous abdominal/peritoneal metastases that are nonobstructing, or following local therapy for individuals with existing or imminent obstruction; **or**
    - Primary treatment for synchronous unresectable metastases of other sites; **or**
    - Primary treatment for unresectable metachronous metastases in individuals who have not received previous adjuvant FOLFOX or CapeOX within the past 12 months, who have received previous fluorouracil/leucovorin (5-FU/LV) or capecitabine therapy, or who have not received any previous chemotherapy; **or**
    - Systemic therapy for unresectable metachronous metastases that remain unresectable after primary treatment; **and**
- Primary treatment for individuals with unresectable metachronous metastases and previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months when:
    - Used in combination with vemurafenib and cetuximab or panitumumab for BRAF V600E mutation positive tumors; **and**

- Subsequent therapy for progression of unresectable advanced or metastatic disease when
    - Used in combination with vemurafenib and cetuximab or panitumumab (if BRAF V600E mutation positive) if previously treated with oxaliplatin and/or irinotecan and if not previously treated with cetuximab or panitumumab

This revised Medical Policy will apply to professional providers and facility claims. The effective date is November 29, 2021.

Place of Service: Outpatient

Please refer to Medical Policy I-109, Irinotecan (Camptosar), for additional information.

Criteria Revised for Panitumumab (Vectibix)

Highmark Blue Shield has revised criteria for Panitumumab (Vextibix). The following revisions have been made:

Colon Cancer has been revised to include the following:

- Therapy for KRAS/NRAS/BRAF wild-type gene and left-sided only tumors in combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen, in individuals appropriate for intensive therapy
- Therapy for KRAS/NRAS/BRAF wild-type gene and left-sided only tumors in combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen, in individuals appropriate for intensive therapy or as a single agent in individuals not appropriate for intensive therapy when used:
    - As adjuvant treatment following synchronized or staged resection for synchronous liver and/or lung metastases that converted from unresectable to resectable disease after primary treatment, **or**
    - As adjuvant treatment following resection and/or local therapy for resectable metachronous metastases in individuals who have received previous chemotherapy; **or**
- Primary treatment in combination with encorafenib for individuals with unresectable metachronous metastases (BRAF V600E mutation positive) and previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months.
- Subsequent therapy in combination with encorafenib for progression of advanced or metastatic disease (BRAF V600E mutation positive) in individuals previously treated:
    - With oxaliplatin-based therapy without irinotecan; **or**
    - With-Irinotecan-based therapy without oxaliplatin; **or**
    - Treatment with oxaliplatin and irinotecan; or
    - FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen; **or**
    - Without irinotecan or oxaliplatin; **or**

- Without irinotecan or oxaliplatin followed by FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) with or without bevacizumab; **or**

Colon Cancer has been updated and the following has been removed:

- Subsequent therapy in combination with irinotecan and vemurafenib for progression of unresectable advanced or metastatic disease (BRAF V600E mutation positive) not previously treated with cetuximab or panitumumab, in individuals previously treated with:
  - Oxaliplatin-based therapy without irinotecan Irinotecan-based therapy without oxaliplatin; **or**
  - FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen; or
  - A fluoropyrimidine without irinotecan or oxaliplatin followed by; or
  - FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) with or without bevacizumab; **or**

Rectal Cancer has been revised to include the following:

- Therapy for KRAS/NRAS/BRAF wild-type gene tumors in combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen in individuals appropriate for intensive therapy:
  - Following palliative radiation therapy (RT) or chemo/RT for synchronous liver only and/or lung only metastases that are unresectable or medically inoperable and remain unresectable (with progression of primary tumor) after primary systemic therapy
- Therapy for KRAS/NRAS/BRAF wild-type gene tumors in combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen
- Primary treatment in combination with encorafenib for individuals with unresectable metachronous metastases (BRAF V600Emutation positive) and previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months; **or**
- Subsequent therapy for progression of advanced or metastatic disease (KRAS/NRAS/BRAF wild-type gene only):
  - In combination with irinotecan or as a single agent for individuals who cannot tolerate irinotecan if previously treated with; **or**
- Subsequent therapy in combination with encorafenib for progression of advanced or metastatic disease (BRAF V600E mutation positive), in individuals previously treated:
  - With oxaliplatin-based therapy without irinotecan; **or**
  - With irinotecan-based therapy without oxaliplatin; **or**
  - With oxaliplatin and irinotecan; **or**
  - Without irinotecan or oxaliplatin; **or**
  - Without irinotecan or oxaliplatin followed by FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) with or without bevacizumab; **or**

Rectal cancer has been updated to remove the following

- Subsequent therapy in combination with irinotecan and vemurafenib for progression of unresectable advanced or metastatic disease (BRAF V600E mutation positive) not previously treated with cetuximab or panitumumab, in individuals previously treated with

- FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen; **or**

- Subsequent therapy in combination with dabrafenib and trametinib or with encorafenib and binimetinib for progression of unresectable advanced or metastatic disease (BRAF V600E mutation positive) not previously treated with cetuximab or panitumumab, in individuals previously treated with:
  - Oxaliplatin-based therapy without irinotecan; **or**
  - Irinotecan-based therapy without oxaliplatin; **or**
  - FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen; **or**
  - A fluoropyrimidine without irinotecan or oxaliplatin followed by FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) with or without bevacizumab.

This revised Medical Policy will apply to professional providers and facility claims. The effective date is November 29, 2021

Place of Service: Outpatient

Please refer to Medical Policy I-117, Panitumumab (Vectibix) for additional information.

Revised criteria for Aqueous Shunts and Stents for Glaucoma

Highmark Blue Shield has revised criteria for Aqueous Shunts and Stents for Glaucoma. The following criteria was updated:

- Insertion of ab externo aqueous shunts approved by the U.S. Food and Drug Administration (FDA) may be considered medically necessary as a method to reduce IOP in individuals with glaucoma where first-line drugs, and second-line drugs have failed to adequately control intraocular pressure (IOP).

- Insertion of ab interno aqueous stents approved by the FDA may be considered medically necessary as a method to reduce IOP in individuals with glaucoma where first-line drugs, and second-line drugs have failed to adequately control intraocular pressure.

This revised Medical Policy will apply to professional providers and/or facility claims. The effective date is August 16, 2021.

Place of Service:

Please refer to Medical Policy S-236, Aqueous Shunts and Stents for Glaucoma, for additional information.

Criteria Revised for Posterior Tibial Nerve Stimulation

Highmark Blue Shield has revised criteria for Z-75, Posterior Tibial Nerve Stimulation (PTNS).

The following indication for PTNS is being removed from the policy:

- Non-obstructive urinary retention

Additional PTNS treatments (greater than 12) medical necessity criteria is being revised to state:

- No documented improvement of symptoms (50% reduction or greater) of urinary frequency, nocturia, and/or urinary urgency.

This revised Medical Policy will apply to professional providers and facility claims. The effective date is November 29, 2021.

Place of Service: Inpatient/Outpatient

Please refer to Medical Policy Z-75, Posterior Tibial Nerve Stimulation, for additional information.

Coverage Guidelines Revised for Irinotecan (Camptosar)

NEWS FOR ALL PROVIDER TYPES

MA MEDICARE ADVANTAGE

Highmark's Medicare Advantage products have revised criteria for Camptosar. The following has been updated:

Bone Cancer, Ewing Sarcoma is being updated to be used as Second-line therapy in combinations with temozolomide with or without vincristine.

Colon Cancer, Adenocarcinoma is being revised as followed:

- Subsequent therapy for progression of advanced or metastatic disease when:
    - Used as a single agent or in FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen with or without bevacizumab (preferred**), ziv-aflibercept, or ramucirumab if previously treated with oxaliplatin-based therapy without irinotecan or with therapy without irinotecan or oxaliplatin; **or**
    - Used in FOLFIRI regimen with cetuximab or panitumumab (KRAS/NRAS/BRAF wild-type only) if previously treated with oxaliplatin-based regimens without irinotecan; **or**
    - Used in combination with cetuximab or panitumumab (KRAS/NRAS/BRAF wild-type only) if previously treated with oxaliplatin and/or irinotecan; **or**

Colon Cancer, Adenocacinoma is being updated to remove

- Subsequent therapy for progression of advanced or metastatic disease when used in combination with vemurafenib and cetuximab or panitumumab (if BRAF V600E mutation positive) if previously treated with oxaliplatin and/or irinotecan and if not previously treated with cetuximab or panitumumab
- primary treatment for individuals with unresectable metachronous metastases and previous adjuvant FOLFOX or CapeOx within the past 12 months when used in combination with vemurafenib and cetuximab or panitumumab for BRAF V600E mutation positive tumors.

Lung Cancer, Small Cell (SCLC) is being updated to remove subsequent systemic therapy for individuals with performance status 0-2 when not used as original regimen and used in combination with cisplatin or carboplatin for primary progressive disease.

Ovarian Cancer-epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer is being updated to remove single agent therapy for persistent disease or recurrence when used in combination with cisplatin for clear cell carcinoma.

Rectal Cancer, Adenocarcinoma is being updated to remove the following:

- Primary treatment with FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin and irinotecan) regimen with cetuximab or panitumumab for synchronous liver only and/or lung only metastases (KRAS/NRAS/BRAF wild-type gene only) that are unresectable or medically inoperable; **or**
    - Used in FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen with or without bevacizumab or with or without cetuximab or panitumumab (KRAS/NRAS/BRAF wild-type gene only) or in FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen with or without bevacizumab as:

- Primary treatment for synchronous liver only and/or lung only metastases that are unresectable or medically inoperable; **or**
- As systemic therapy for synchronous liver only and/or lung only metastases that are unresectable or medically inoperable and remain unresectable (with no progression of primary tumor) after primary systemic therapy; **or**
- As systemic therapy following short-course radiation therapy (RT) or chemo/RT for synchronous liver only and/or lung only metastases that are unresectable or medically inoperable and remain unresectable (with progression of primary tumor) after primary systemic therapy; **or**
- Primary treatment for synchronous abdominal/peritoneal metastases that are nonobstructing, or following local therapy for individuals with existing or imminent obstruction; **or**
- Primary treatment for synchronous unresectable metastases of other sites; **or**
- Primary treatment for unresectable metachronous metastases in individuals who have not received previous adjuvant FOLFOX or CapeOX within the past 12 months, who have received previous fluorouracil/leucovorin (5-FU/LV) or capecitabine therapy, or who have not received any previous chemotherapy; **or**
- Systemic therapy for unresectable metachronous metastases that remain unresectable after primary treatment; **and**

- Primary treatment for individuals with unresectable metachronous metastases and previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months when:
  - Used in combination with vemurafenib and cetuximab or panitumumab for BRAF V600E mutation positive tumors; **and**
- Subsequent therapy for progression of unresectable advanced or metastatic disease when
  - Used in combination with vemurafenib and cetuximab or panitumumab (if BRAF V600E mutation positive) if previously treated with oxaliplatin and/or irinotecan and if not previously treated with cetuximab or panitumumab

This revised Medical Policy will apply to professional providers and facility claims. The effective date is November 29, 2021.

Place of Service: Outpatient

Please refer to Medicare Advantage Medical Policy I-24, Irinotecan (Camptosar), for additional information.

Criteria Revised for Panitumuab (Vectibix)

NEWS FOR ALL PROVIDER TYPES

MA MEDICARE ADVANTAGE

Highmark's Medicare Advantage products have revised criteria for Panitumumab (Vectibix). The following revisions have been made:

Colon Cancer has been revised to include the following:

- Therapy for KRAS/NRAS/BRAF wild-type gene and left-sided only tumors in combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen, in individuals appropriate for intensive therapy
- Therapy for KRAS/NRAS/BRAF wild-type gene and left-sided only tumors in combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen, in individuals appropriate for intensive therapy or as a single agent in individuals not appropriate for intensive therapy when used:
    - As adjuvant treatment following synchronized or staged resection for synchronous liver and/or lung metastases that converted from unresectable to resectable disease after primary treatment, **or**
    - As adjuvant treatment following resection and/or local therapy for resectable metachronous metastases in individuals who have received previous chemotherapy
- Primary treatment in combination with encorafenib for individuals with unresectable metachronous metastases (BRAF V600E mutation positive) and previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months.
- Subsequent therapy in combination with encorafenib for progression of advanced or metastatic disease (BRAF V600E mutation positive) in individuals previously treated:
    - With oxaliplatin-based therapy without irinotecan; **or**
    - With-Irinotecan-based therapy without oxaliplatin; **or**
    - Treatment with oxaliplatin and irinotecan; or
    - FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen; **or**
    - Without irinotecan or oxaliplatin; **or**
    - Without irinotecan or oxaliplatin followed by FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) with or without bevacizumab

Colon Cancer has been updated and the following has been removed:

- Subsequent therapy in combination with irinotecan and vemurafenib for progression of unresectable advanced or metastatic disease (BRAF V600E mutation positive) not previously treated with cetuximab or panitumumab, in individuals previously treated with:
    - Oxaliplatin-based therapy without irinotecan Irinotecan-based therapy without oxaliplatin; **or**
    - FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen; or
    - A fluoropyrimidine without irinotecan or oxaliplatin followed by; or
    - FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) with or without bevacizumab

Rectal Cancer has been revised to include the following:

- Therapy for KRAS/NRAS/BRAF wild-type gene tumors in combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen in individuals appropriate for intensive therapy:
    - Following palliative radiation therapy (RT) or chemo/RT for synchronous liver only and/or lung only metastases that are unresectable or medically inoperable and remain unresectable (with progression of primary tumor) after primary systemic therapy
- Therapy for KRAS/NRAS/BRAF wild-type gene tumors in combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen
- Primary treatment in combination with encorafenib for individuals with unresectable metachronous metastases (BRAF V600Emutation positive) and previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months
- Subsequent therapy in combination with encorafenib for progression of advanced or metastatic disease (BRAF V600E mutation positive), in individuals previously treated:
    - With oxaliplatin-based therapy without irinotecan; **or**
    - With irinotecan-based therapy without oxaliplatin; **or**
    - With oxaliplatin and irinotecan; **or**
    - Without irinotecan or oxaliplatin; **or**
    - Without irinotecan or oxaliplatin followed by FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) with or without bevacizumab

Rectal cancer has been updated to remove the following

- Subsequent therapy in combination with irinotecan and vemurafenib for progression of unresectable advanced or metastatic disease (BRAF V600E mutation positive) not previously treated with cetuximab or panitumumab, in individuals previously treated with
    - FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen
- Subsequent therapy in combination with dabrafenib and trametinib or with encorafenib and binimetinib for progression of unresectable advanced or metastatic disease (BRAF V600E mutation positive) not previously treated with cetuximab or panitumumab, in individuals previously treated with:
    - Oxaliplatin-based therapy without irinotecan; **or**
    - Irinotecan-based therapy without oxaliplatin; **or**
    - FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen; **or**
    - A fluoropyrimidine without irinotecan or oxaliplatin followed by FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) with or without bevacizumab.

This revised Medical Policy will apply to professional providers and facility claims. The effective date is November 29, 2021.

Place of Service: Outpatient

Please refer to Medicare Advantage Medical Policy I-117, Panitumumab (Vectibix) for additional information.

Comments on these new medical policies?

We want to know what you think about our new medical policy changes. Send us an email with any questions or comments that you may have on the new medical policies in this edition of *Medical Policy Update*.

Write to us at **medicalpolicy@highmark.com**.

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About this newsletter

Medical Policy Update is the monthly newsletter for most health care professionals (and office staff) and facilities who participate in our networks and submit claims to Highmark using the 837P HIPAA transaction or the CMS 1500 form, or the 837I HIPAA transaction.

Medical Policy Update focuses only on medical policy and claims administration updates, including coding guidelines and procedure code revisions, and is the sole source for this information. For all other news, information and updates, be sure to read *Provider News*, available on the Provider Resource Center at **www.highmarkblueshield.com**.

Inquiries about Eligibility, Benefits, Claims Status or Authorizations
For inquiries about eligibility, benefits, claim status or authorizations, Highmark Blue Shield encourages providers to use the electronic resources available to them - NaviNet® and the applicable HIPAA transactions – prior to placing a telephone call to the Provider Service Center at 1-866-803-3708.

Acknowledgement

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