Post-Mastectomy Surgery and Services
Clinical Coverage Criteria

Overview

The Women's Health and Cancer Rights Act of 1998 (WHCRA) is a federal law that provides protections to patients who choose to have breast reconstruction in connection with a mastectomy. The WHCRA, enacted October 21, 1998, amended the Public Health Service Act (PHS Act) and the Employee Retirement Income Security Act of 1974 (ERISA). The WHCRA is administered by the Department of Health and Human Services and the Department of Labor. The WHCRA applies to group health plans and individual insurance policies. Group heath plans can either be insured or self-funded. The WHCRA does not apply to Medicare or Medicaid.

As required by the Women's Health and Cancer Rights Act (WHCRA) of 1998, Fallon Health provides coverage for the following services in a manner determined in consultation with the attending physician and the plan member:

- All stages of reconstruction of the breast on which the mastectomy has been performed;
- Surgery and reconstruction of the other breast to produce a symmetrical appearance;
- Prostheses; and
- Treatment of physical complications of mastectomy, including lymphedema.

Coverage cannot be denied based upon the period of time between the mastectomy and the request for reconstructive surgery; because the member had the mastectomy prior to joining a plan; or because the mastectomy was not as a result of cancer. Also, despite the title, nothing in the law limits WHCRA entitlements to women.

The WHCRA does not prohibit health plans from imposing copayments, deductibles, or coinsurance requirements on health benefits in connection with a mastectomy and reconstruction as long as such requirements are consistent with those established for other benefits under the plan. Please consult the individual plan benefits for specific information.

Policy

This Policy applies to the following Fallon Health products:

☒ Commercial
☒ Medicare Advantage
☒ MassHealth ACO
☒ NaviCare
☒ PACE

Fallon Health requires prior authorization for post-mastectomy surgery and services.

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations. Fallon Health's Clinical Coverage Criteria are developed in

accordance with Medicare Managed Care Manual, Chapter 4, Sections 10.16 – Medical Necessity and 90.5 Creating New Guidance.

Medicare has an NCD for Breast Reconstruction Following Mastectomy (140.2, Version 1, Effective Date of this Version: 01/01/1997). Per NCD 140.2, reconstruction of the affected and the contralateral unaffected breast following a medically necessary mastectomy are covered. National Government Services, Inc., the Medicare Administrative Contractor (MAC) with jurisdiction in our service area has an LCD for Reduction Mammaplasty (L35001) and an LCA Billing and Coding: for Reduction Mammaplasty (A56837). Reduction mammaplasty may be performed to reduce the size of the contralateral unaffected breast to bring it into symmetry with a breast reconstructed after cancer surgery. Noridian Healthcare Solutions, LLC, the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) with jurisdiction in our service area has an LCD for External Breast Prostheses (L33317) and an LCA for External Breast Prostheses – Policy Article (A52478) (MCD search 02/27/2023).

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. When there is no Medicare guidance, or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health Clinical Coverage Criteria will be used for medical necessity determinations, except as otherwise provided herein.* Fallon Health's Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204 and are therefore no more restrictive than MassHealth medical necessity guidelines.

* Fallon Health will follow *MassHealth Guidelines for Medical Necessity Determination for Breast Reconstruction* when making medical necessity determinations for breast reconstruction for NaviCare members, when the member does not meet medical necessity criteria in Medicare guidance. Fallon Health will follow MassHealth Prosthetics Manual program regulations (130 CMR 428.00) when making medical necessity determinations for external breast prostheses and related supplies for NaviCare members, when the member does not meet medical necessity criteria in Medicare guidance, or when MassHealth provides additional coverage.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as approved by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be approved by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria will be used for medical necessity determinations for MassHealth ACO members, except as otherwise provided herein.* Fallon Health's Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204 and are therefore no more restrictive than MassHealth medical necessity guidelines.

* Fallon Health will follow *MassHealth Guidelines for Medical Necessity Determination for Breast Reconstruction* when making medical necessity determinations for breast reconstruction for MassHealth ACO members. Fallon Health will follow MassHealth Prosthetics Manual program regulations (130 CMR 428.00) when making medical necessity determinations for external breast prostheses and related supplies for MassHealth ACO members.

Part I. Commercial
Fallon Health Clinical Coverage Criteria

The following services are covered for commercial plan members in accordance with the Women's Health and Cancer Rights Act (WHCRA):

- All stages of reconstruction of the breast on which the mastectomy was performed, including but not limited to:
  - Prosthetic implant reconstruction with tissue expander
  - Nipple/areolar reconstruction and/or tattooing
- Surgery of the contralateral breast to achieve a symmetrical appearance, including but not limited to:
  - Mastopexy
  - Reduction mammoplasty
  - Augmentation mammoplasty, with or without prosthetic implant
- Revision of a previously reconstructed breast or revision of a procedure performed on the contralateral breast for medically necessary indications, including but not limited to removal and replacement of prosthetic implants, or to achieve symmetry.
- Prostheses and treatment of physical complications at all stages of a mastectomy, including lymphedemas.
  - One prefabricated external breast prosthesis is covered for the useful lifetime of the prosthesis (two breast prostheses, one per side, are covered for women who have had bilateral mastectomies).
  - The useful lifetime expectancy for a silicone breast prosthesis (HCPCS code L8030) is two years. For fabric, foam, or fiber filled breast prostheses (HCPCS code L8001, L8002, L8020), the useful lifetime expectancy is 6 months. Replacement sooner than the useful lifetime is not covered, except when the prosthesis is lost or irreparably damaged (this does not include ordinary wear and tear), or the plan member's condition changes such that the current equipment no longer meets the plan member's needs.
  - A breast prosthesis may be attached to the chest wall with an adhesive skin support (HCPCS code A4280) or worn in a mastectomy bra (HCPCS code L8000), which is specially designed with a pocket to hold the prosthesis in place. A mastectomy bra (L8000) is covered for a plan member who has an external breast prosthesis (L8020, L8030) when the pocket of the bra is used to hold the prosthesis. Fallon Health covers two mastectomy bras (HCPCS code L8000, L8001, L8002) per calendar year.
  - A post-mastectomy camisole-type undergarment (HCPCS code L8015) is covered for use during the post-operative period, or as an alternative to a breast prosthesis and mastectomy bra. The garment includes breast forms. Fallon Health covers two post-mastectomy camisole-type (HCPCS code L8015) garments per calendar year.
  - A mastectomy sleeve (L8010) is covered for the treatment of lymphedema. Fallon Health covers two mastectomy sleeves per calendar year.

Part II. Fallon Medicare Plus, NaviCare

Breast reconstruction

Fallon Health follows NCD Breast Reconstruction Following Mastectomy (140.2), LCD Reduction Mammaplasty (L35001) and LCA Billing and Coding: for Reduction Mammaplasty (A56837) when making medical necessity determinations for breast reconstruction for Fallon Medicare Plus and NaviCare members.

Fallon Health will follow *MassHealth Guidelines for Medical Necessity Determination for Breast Reconstruction* when making medical necessity determinations for breast reconstruction for NaviCare members, when the member does not meet medical necessity criteria in Medicare guidance. See Part III. below.

Links
NCD: **Breast Reconstruction Following Mastectomy (140.2)**
LCD: Reduction Mammaplasty (L35001)
LCA: Billing and Coding: for Reduction Mammaplasty (A56837)

Reconstruction of the affected and the contralateral unaffected breast following a medically necessary mastectomy are covered (NCD 140.2).

Reduction mammaplasty to reduce the size of the contralateral unaffected breast to bring it into symmetry with a breast reconstructed after cancer surgery is covered (L35001).

Breast prostheses

Fallon Health follows LCD External Breast Prostheses (L33317) and an LCA External Breast Prostheses – Policy Article (A52478) when making medical necessity determinations for external breast prostheses and related supplies for Fallon Medicare Plus and NaviCare members.

Fallon Health will follow MassHealth Prosthetics Manual program regulations (130 CMR 428.00) when making medical necessity determinations for external breast prostheses and related supplies for NaviCare members, when the member does not meet medical necessity criteria in Medicare guidance, and when MassHealth provides additional coverage. See Part III below.

Links
LCD: External Breast Prostheses (L33317)
LCA: External Breast Prostheses – Policy Article (A52478)

- One external breast prosthesis (L8020, L8030) is covered for a plan member who has had a mastectomy. Two external breast prostheses (one per side) are covered for a plan members who have had bilateral mastectomies. Refer to the ICD-10 code list in the related Policy Article (A52478) for applicable diagnoses.
  - The useful lifetime of a foam breast prosthesis (L8001, L8002, L8020) is six months.
  - The useful lifetime of a silicone breast prosthesis (L8030) is 2 years.
  - An external breast prosthesis of the same type can be replaced at any time if it is lost or irreparably damaged (this does not include ordinary wear and tear), or if the plan member's condition changes such that the current equipment no longer meets the plan member's needs.
- Codes L8001 and L8002 describe a mastectomy bra with integrated breast prosthesis, either unilateral or bilateral, respectively. Products described by codes L8001 and L8002 are covered as an alternative to an external breast prosthesis (L8020, L8030) and mastectomy bra (L8000).
- A mastectomy bra (L8000) is covered for a plan member who has a covered breast prosthesis (L8020, L8030) when the pocket of the bra is used to hold the prosthesis. The LCD does not specify quantities of bras or camisoles (L8000, L8001, L8002 :8015) that are covered. A physician determines what is reasonable and necessary on a case-by-case basis. Medical records should reflect and support what is ordered and dispensed to a plan member. Regardless of utilization, a supplier may not dispense more than a three (3) month quantity at one time.
- Code A4280 should be used when billing for an adhesive skin support that attaches an external breast prosthesis directly to the chest wall (obviating the need for a mastectomy bra).
- A camisole-type garment with mastectomy form (L8015) is covered for use in the postoperative period prior to a permanent breast prosthesis or as an alternative to a breast prosthesis and mastectomy bra.
- A mastectomy sleeve (L8010) is noncovered, since it does not meet the definition of a prosthesis.
- Breast prostheses with integral adhesive (L8031) have not been demonstrated to have a clinical advantage over those without the integral adhesive. Therefore, if L8031 is billed, it will be denied as not covered.
- The medical necessity for the additional features of a custom fabricated prosthesis (L8035) compared to a prefabricated silicone breast prosthesis has not been established, and therefore, if an L8035 breast prosthesis is billed, it will be denied as not covered.

Part III. MassHealth, NaviCare

Breast reconstruction

Fallon Health follows *MassHealth Guidelines for Medical Necessity Determination for Breast Reconstruction* when making coverage determinations for breast reconstruction for MassHealth ACO members.

Fallon Health will follow *MassHealth Guidelines for Medical Necessity Determination for Breast Reconstruction* when making medical necessity determinations for breast reconstruction for NaviCare members, when the member does not meet medical necessity criteria in Medicare guidance. See Part II above.

Link:
MassHealth Guidelines for Medical Necessity Determination for Breast Reconstruction
(Revised policy effective: November 8, 2022; Supersedes policy dated March 12, 2018)

Clinical Coverage Criteria
MassHealth bases its determination of medical necessity for breast reconstruction on clinical data including, but not limited to, indicators that would affect the relative risks and benefits of the procedure, including post-operative recovery. These criteria include, but are not limited to, the following:

1. A comprehensive medical history and physical exam has been conducted by the surgeon to evaluate the need for breast reconstruction surgery.
2. The breast reconstruction surgery is intended to correct, restore, or improve anatomical and/or functional impairments that have resulted from congenital anomalies, accidental injury, trauma, previous surgery, including mastectomy or lumpectomy; therapeutic interventions (for example, radiation); or condition/disease of the breast.
3. A surgical treatment plan that outlines the type of techniques and stages of the procedure(s) that will be performed has been developed.
4. When the proposed surgery follows a mastectomy that has been performed to remove a malignant neoplasm or carcinoma in situ of the breast or has been performed prophylactically to reduce the risk of breast cancer in high-risk members, breast reconstruction in connection with a mastectomy may include:
    a. Reconstruction by an implant-based approach or through the use of autologous tissue, as well as nipple reconstruction, to restore shape of the affected breast.
    b. Surgery for the nondiseased/unaffected/contralateral breast, which may involve augmentation mammoplasty, reduction mammoplasty, and/or mastopexy to achieve breast symmetry.

Noncoverage
MassHealth does not consider breast reconstruction surgery to be medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to, the following:

1. Breast reconstruction that is performed for the exclusive purpose of altering appearance and is unrelated to physical disease or defect or traumatic injury.
2. Breast reconstruction after prophylactic mastectomy performed to reduce risk of breast cancer in women who are not high risk.
3. Replacement of breast implants placed for cosmetic purposes or reconstruction following removal of breast implant originally place for cosmetic purposes, when performed in the absence of breast cancer or other covered indications.

MassHealth does not consider breast implant removal to be medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to, the removal of asymptomatic, intact breast implants except for cases of cancer diagnosis and treatment as described previously.

Breast prostheses

Fallon Health follows MassHealth Prosthetics Manual program regulations (130 CMR 428.00) when making coverage determinations for external breast prostheses and related supplies for MassHealth ACO members.

Fallon Health will follow MassHealth Prosthetics Manual program regulations (130 CMR 428.00) when making medical necessity determinations for external breast prostheses and related supplies for NaviCare members, when the member does not meet medical necessity criteria in Medicare guidance, or when MassHealth provides additional coverage. See Part II above.

Only those prosthetics listed in Subchapter 6 of the Prosthetics Manual are covered, subject to requirements and limitations found in the MassHealth Orthotics and Prosthetics Payment and Coverage Guideline Tool.

Breast prostheses and related supplies must be medically necessary in accordance with 130 CMR 450.204 and reasonable for the treatment of the member's condition.

Breast prostheses and related supplies are not covered when:
(1) they cannot reasonably be expected to make a meaningful contribution to the treatment of the member's condition or the performance of the member's activities of daily living; or
(2) they are more costly than a medically comparable and suitable alternative or that serves essentially the same purpose as equipment already available to the member.

Links
Program regulations: Prosthetics Manual Program Regulations (130 CMR 428.00)
Payment and coverage guideline tool: Orthotics and Prosthetics Payment and Coverage Guideline Tool

- One external breast prosthesis (L8020, L8030) is covered for a plan member who has had a mastectomy. Two external breast prostheses (one per side) are covered for plan members who have had bilateral mastectomies.
  - The useful lifetime of a foam breast prosthesis (L8001, L8002, L8020) is seven months.
  - The useful lifetime of a silicone breast prosthesis (L8030) is seven months.
  - An external breast prosthesis of the same type can be replaced at any time if it is lost or irreparably damaged (this does not include ordinary wear and tear), or if the plan member’s condition changes such that the current equipment no longer meets the plan member’s needs.
- Codes L8001 and L8002 describe a mastectomy bra with integrated breast prosthesis, either unilateral or bilateral, respectively. Products described by codes L8001 and L8002 are covered as an alternative to an external breast prosthesis (L8020, L8030) and mastectomy bra (L8000). Two mastectomy bras with integrated breast prosthesis are covered per seven months.
- A mastectomy bra (L8000) is covered for a plan member who has a covered breast prosthesis (L8020, L8030) when the pocket of the bra is used to hold the prosthesis. Two mastectomy bras (L8000) are covered per seven months.
- Code A4280 should be used when billing for an adhesive skin support that attaches an external breast prosthesis directly to the chest wall (obviating the need for a mastectomy bra).
- A camisole-type garment with mastectomy form (L8015) is covered for use in the postoperative period prior to a permanent breast prosthesis or as an alternative to a breast prosthesis and mastectomy bra. Two camisole-type garments are covered per seven months.
- A mastectomy sleeve (L8010) is covered for the treatment of lymphedema. Two mastectomy sleeves are covered per seven months.
- A breast prosthesis with integral adhesive (L8031) is covered as an alternative to an external breast prosthesis (L8020, L8030); mastectomy bra with integrated breast prosthesis (L8001,

L8002) and camisole-type garment with mastectomy form (L8015). The useful lifetime of a breast prosthesis with integral adhesive is one year.

- One prefabricated nipple prosthesis (L8032) is covered per year (two for a plan member with bilateral mastectomies).
- A custom fabricated breast prosthesis (L8035) is covered as an alternative to a prefabricated external breast prosthesis (L8020, L8030); mastectomy bra with integrated breast prosthesis (L8001, L8002) and camisole-type garment with mastectomy form (L8015). Prior authorization is required for custom fabricated breast prosthesis (L8035). The following documentation must be submitted by the provider:
  - A copy of the written prescription signed by a licensed physician or independent nurse practitioner. The written prescription must include medical justification for the custom fabricated breast prosthesis (per 428.409: Prescription Requirements).
  - A copy of the evaluation performed by a licensed prosthetist or certified mastectomy fitter which concludes that a custom fabricated breast prostheses is useful to the member given the member's physical condition (per 428.412: Prior Authorization and 428.413: Procedure for Requesting Prior Authorization).

  One custom breast prosthesis is covered per year (two for a plan member with bilateral mastectomies).

Exclusions

- The additional features of a custom fabricated breast prosthesis (L8035) are not medically necessary. A custom fabricated breast prosthesis is covered for MassHealth ACO and NaviCare plan members in accordance with Subchapter 6 of the MassHealth Prosthetics Manual (prior authorization is required).
- The additional features of a custom fabricated nipple prosthesis (L8033) are not medically necessary.
- The additional features of a breast prostheses with integral adhesive (L8031) are not medically necessary. Breast prostheses with integral adhesive have not been demonstrated to have a clinical advantage over those without the integral adhesive. A breast prosthesis with integral adhesive is covered for MassHealth and NaviCare members in accordance with Subchapter 6 of the MassHealth Prosthetics Manual (prior authorization is required).

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

S2066, S2067, S2068

These codes were established in 2006 (S2068) and in 2007 (S2066 and S2067) to describe new methods of breast reconstruction that had not reached the sufficient literature and utilization threshold to apply for Current Procedural Terminology (CPT) Category I Code status. Since that time, the procedures represented by these three codes have grown in acceptance, and in 2011, the American Medical Association (AMA) identified CPT code 19364 as the appropriate code for breast reconstruction with free flap procedures, regardless of the free flap technique used. In 2021, the descriptor for CPT code 19364 was modified to read "Breast reconstruction; with free flap (e.g., fTRAM, DIEP, SIEA, GAP flap)." S2066, S2067 and S2068 are not payable by Medicare or MassHealth. In 2021, the Blue Cross and Blue Shield Association submitted a request to CMS to discontinue the S codes related to breast reconstruction. HCPCS codes S2066, S2067, and S2068 will be discontinued by CMS on December 31, 2024.

Effective for dates of service on or after 6/1/2023, Fallon Health will not reimburse HCPCS codes S2066, S2067 and S2068 for any line of business as all procedures reimbursable under these S codes are reimbursable under CPT code 19364.

Breast reconstruction

Code	Description
19316	Mastopexy

19318	Breast reduction
19325	Breast augmentation with implant
19328	Removal of intact breast implant
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)
19340	Insertion of breast implant on same day of mastectomy (ie immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
19350	Nipple/areola reconstruction
19357	Tissue expander placement in breast reconstruction, including subsequent expansions(s)
19361	Breast reconstruction; with latissimus dorsi flap
19364	Breast reconstruction; with free flap (eg fTRAM, DIEP, SIEA, GAP flap)
19367	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap, including closure of donor site
19368	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous flap (TRAM), requiring separate microvascular anastomosis (supercharging)
19369	Breast reconstruction; with bipedicled transverse rectus abdominis myocutaneous flap (TRAM)
19370	Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy
19371	Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents
19380	Revision of reconstructed breast (eg, significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)
19396	Preparation of moulage for custom breast implant

External breast prostheses and related supplies

Code	Description
A4280	Adhesive skin support attachment for use with external breast prosthesis, each
L8000	Breast prosthesis, mastectomy bra, without integrated breast prosthesis form, any size, any type
L8001	Breast prosthesis, mastectomy bra, with integrated breast prosthesis form, unilateral, any size, any type
L8002	Breast prosthesis, mastectomy bra, with integrated breast prosthesis form, bilateral, any size, any type
L8010	Breast prosthesis, mastectomy sleeve
L8015	External breast prosthesis garment, with mastectomy form, post-mastectomy
L8020	Breast prosthesis, mastectomy form
L8030	Breast prosthesis, silicone or equal, without integral adhesive
L8031	Breast prosthesis, silicone or equal, with integral adhesive
L8032	Nipple prosthesis, prefabricated, reusable, any type, each
L8033	Nipple prosthesis, custom fabricated, reusable, any material, any type, each
L8035	Custom breast prosthesis post mastectomy, molded to patient
L8039	Breast prosthesis, not otherwise specified

References

1. United States Code, Title 29, Chapter 18, Subchapter 1, Subtitle B, Part 7, Subpart B, § 1185b. Required coverage for reconstructive surgery following mastectomies.
2. Medicare National Coverage Determination (NCD) for Breast Reconstruction Following Mastectomy (140.2). Effective Date 01/01/1997. Accessed 02/27/2023.
3. Noridian Healthcare Solutions, LLC. LCD for External Breast Prostheses (L33317). Original Effective Date 10/01/2015. Revision Effective Date 01/01/2020. Accessed 02/27/2023.
4. Noridian Healthcare Solutions, LLC. Local Coverage Article (LCA) External Breast Prostheses - Policy Article (A52478). Original Effective Date 10/01/2015. Revision Effective Date 01/01/2020. Accessed 02/27/2023.
5. National Government Services, Inc. Local Coverage Determination (LCD): Reduction Mammaplasty (L35001) Original Effective Date 10/1/2015. Revision Effective Date 11/7/2019. Accessed 02/27/2023.
6. National Government Services, Inc. Local Coverage Article (LCA): Reduction Mammaplasty (A56837). Original Effective Date 11/7/2019. Revision Effective Date 1/1/2021. Accessed 02/27/2023.
7. MassHealth Guidelines for Medical Necessity Determination for Breast Reconstruction and Breast Implant Removal. Revised policy effective: November 8, 2022. Supersedes policy dated March 12, 2018. Accessed 02/27/2023.
8. MassHealth Prosthetics Manual. Program Regulations 130 CMR 428.00. Effective 12/15/17.

Policy history

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Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.