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 Policy Number: C10276-A

Tysabri (natalizumab)

PRODUCTS AFFECTED

Tysabri (natalizumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:

Relapsing form of multiple sclerosis (relapsing-remitting multiple sclerosis, secondary-progressive multiple sclerosis with relapses, progressive-relapsing multiple sclerosis), to include clinically isolated syndrome, Moderately to severely active Crohn's disease

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. FOR ALL INDICATIONS:

1. Negative anti-JCV (John Cunningham Virus) antibody test within the past 3 months OR prescriber attestation that member tested positive for JCV antibody test and member has been counseled on the higher risk of therapy causing a development of PML

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AND

2. Prescriber attests member is NOT receiving any other disease-modifying MS agent, immunosuppressants, or TNF inhibitors (e.g., adalimumab, infliximab)
AND
3. Prescriber attests member will be monitored for any new sign or symptom that may be suggestive of PML
AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to TYSABRI (natalizumab) include: Patients who have or have had PML, Patients who have had a hypersensitivity reaction to TYSABRI]

B. MODERATE TO SEVERE ACTIVE CROHN'S DISEASE:

1. Documentation of a diagnosis of Crohn's Disease
AND
2. Member has one or more high risk feature:
 - i. Diagnosis at a younger age (<30 years old)
 - ii. History of active or recent tobacco use
 - iii. Elevated C-reactive protein and/or fecal calprotectin levels
 - iv. Deep ulcers on colonoscopy
 - v. Long segments of small and/or large bowel involvement
 - vi. Perianal disease
 - vii. Extra-intestinal manifestations
 - viii. History of bowel resectionsAND
3. (a) Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (> 3 months) of ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine, methotrexate) up to maximally indicated doses
OR
(b) Prescriber provides documented medical justification that supports the inability to use immunomodulators
 - i. Inability to induce short-term symptomatic remission with a 3-month trial of systemic glucocorticoids
 - ii. High risk factors for intestinal complications may include: Initial extensive ileal, ileocolonic, or proximal GI involvement, Initial extensive perianal/severe rectal disease, Fistulizing disease (e.g., perianal, enterocutaneous, and rectovaginal fistulas), Deep ulcerations, Penetrating, stricturing or stenosis disease and/or phenotype, Intestinal obstruction or abscess
 - iii. High risk factors for postoperative recurrence may include: Less than 10 years duration between time of diagnosis and surgery, Disease location in the ileum and colon, Perianal fistula, Prior history of surgical resection, Use of corticosteroids prior to surgeryAND
4. Documented treatment failure, serious side effects or clinical contraindication to an adequate trial of one TNF-inhibitor
AND
5. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
6. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s) [DOCUMENTATION REQUIRED]

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C. MULTIPLE SCLEROSIS

1. Documentation of diagnosis of a relapsing form of multiple sclerosis (relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS, or clinically isolated syndrome)
AND
2. (a) Documentation of ****inadequate response** (trial of 3 months) to ONE of the following: ONE of Interferon therapy (Avonex, Rebif, Extavia, Betaseron, Plegridy) OR Glatiramer OR formulary oral disease modifying therapy [e.g., Aubagio (teriflunomide), Tecfidera (dimethyl fumarate), Gilenya (fingolimod), etc.]
****Inadequate response** is defined as meeting at least TWO (2) of the following three criteria during treatment: 1) Clinical relapses (at least two relapses within the past 12 months), 2) CNS lesions progression as measured by MRI, OR 3) Worsening disability (e.g., sustained worsening of EDSS score or neurological exam findings; worsening disability include, but not limited to, decreased mobility, decreased ability to perform activities of daily living due to disease progression, or EDSS > 3.5)
OR
(b) Documentation member has indicators of a highly active course of multiple sclerosis: (i) age of MS onset > 40 years of age, (ii) male gender, (iii) African American, (iv) motor, sphincter, brainstem-cerebellar symptoms, (v) MRI lesions in brainstem or spina cord, OR (vi) ≥ 2 acute relapses in first 2 years of onset with significant sustained disability following relapse
AND
3. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s) [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Negative anti-JCV (John Cunningham Virus) antibody test within the past 12 months OR prescriber attestation that member tested positive for JCV antibody test and member has been counseled on the higher risk of therapy causing a development of PML
AND
2. For continuation of therapy requests at 24 months or beyond: Prescriber attests that member and/or caregiver has been informed about the risks of Tysabri, including that the risk of PML increases with longer treatment duration, and re-instruction on the early signs and symptoms of PML
AND
3. Adherence to therapy at least 85% of the time as verified by prescriber and member fill history
AND
4. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity [e.g., hypersensitivity reactions, hepatotoxicity, signs or symptoms of PML, development of severe infections (including pneumonias, pneumocystis carinii pneumonia, pulmonary mycobacterium avium intracellulare, bronchopulmonary aspergillosis, herpes, urinary tract infections, gastroenteritis, vaginitis, tonsillitis, meningitis)]

B. CROHN'S DISEASE

1. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms [DOCUMENTATION REQUIRED]
AND
2. Prescribed for use as monotherapy only (not prescribed for combination use with immunosuppressants or inhibitors of TNF- α)

C. MULTIPLE SCLEROSIS

1. Documentation of positive clinical response or stable disease based on ONE of the following:

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- (a) Documentation of a stable number or decrease in acute attacks (relapses) within the last 6 months
- OR
- (b) Documentation of lack of progression or sustained disability
- OR
- (c) Recent (within the last 6 months) MRI shows lack of development of new asymptomatic lesions

DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Multiple Sclerosis: Prescribed by or in consultation with board certified neurologist or Multiple sclerosis physician specialist

Crohn's Disease: Prescribed by or in consultation with board certified gastroenterologist or colorectal surgeon

[If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

300 mg every 4 weeks

PLACE OF ADMINISTRATION:

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for Tysabri (natalizumab). For information on site of care, see

[Specialty Medication Administration Site of Care Coverage Criteria \(molinamarketplace.com\)](https://www.molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Intravenous Infusion

DRUG CLASS:

Multiple Sclerosis Agents - Monoclonal Antibodies

FDA-APPROVED USES:

Multiple sclerosis (MS): As monotherapy for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Tysabri increases the risk of PML. When initiating and continuing treatment with Tysabri, physicians should consider whether the expected benefit of Tysabri is sufficient to offset this risk.

Crohn's disease (CD): For inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF- α . *Important limitations: In CD, Tysabri should not be used in combination with immunosuppressants or inhibitors of TNF alpha.*

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX**APPENDIX:**

None

BACKGROUND AND OTHER CONSIDERATIONS**BACKGROUND:**

Multiple Sclerosis (MS) is a chronic autoimmune disease that degrades the protective myelin sheath that covers nerve cells in the central nervous system, specifically in the areas of the brain, spinal cord, and optic nerves. For most Americans, the risk of developing MS is approximately 0.1% but the risk is increased for individuals with a first-degree relative with MS. MS occurs at least two to three times more commonly in women than in men. Most patients are diagnosed between the ages of 20 to 50 years. Relapsing remitting MS (RRMS) is the most common type of MS affecting approximately 85% of the patients initially diagnosed with MS. Complications of MS include fatigue, loss of coordination, visual problems, cognitive and sexual dysfunction, depression, spasticity, and pain.

Clinically, MS presents with four relatively distinguishable patterns based on the course of disease. Of the four clinical subtypes of MS (primary progressive, progressive relapsing, RRMS and secondary progressive), RRMS is the most common and is characterized by acute relapses followed by partial or full recovery.

1. Relapsing–remitting MS: the most common form, affecting about 85% of MS patients. It is marked by flare-ups (relapses or exacerbations) of symptoms followed by periods of remission when symptoms improve or disappear.
2. Secondary progressive MS: may develop in some patients with relapsing–remitting disease. For many patients, treatment with disease-modifying agents helps delay such progression. The disease course continues to worsen with or without periods of remission or leveling off of symptom severity (plateaus).
3. Primary progressive MS affects approximately 10% of MS patients. Symptoms continue to worsen gradually from the beginning. There are no relapses or remissions, but there may be occasional plateaus. This form of MS is more resistant to the drugs typically used to treat the disease.
4. Progressive-relapsing MS: PRMS affects about 5% of patients. It is characterized by continuous neurologic decline from the time of diagnosis, accompanied by distinct attacks. It is progressive from the start, with intermittent flare-ups of worsening symptoms along the way. There are no periods of remission.

Crohn's disease (CD) is a chronic, inflammatory, multisystem disorder of unknown etiology with genetic, immunologic, and environmental influences. CD involves any area of the gastrointestinal tract (GIT) from the oral cavity to the anus, but it is limited primarily to the colon with or without small- intestine disease. Moreover, the inflammation in CD is often described as transmural, damaging each mucosal layer of the GIT, and noncontinuous. Therapy for CD includes medical therapy with pharmacologic agents consisting of 5-aminosalicylates (5-ASA), antibiotics, corticosteroids, immunomodulators, and biologics. Surgery is reserved for patients who are refractory to medical therapy. The key symptoms of CD include abdominal pain, diarrhea, and fatigue. Weight loss, fever, growth failure, anemia, recurrent fistulas, or extraintestinal manifestations (e.g., arthritis, iritis) can also occur. There is no single laboratory test that can make an unequivocal diagnosis of CD. The anti-tumor necrosis factor (anti-TNF) agents (infliximab, adalimumab, and certolizumab pegol) are effective for treatment of patients with CD who respond inadequately to treatment with corticosteroids, thiopurines, and methotrexate. Other monoclonal antibodies approved for CD are the integrin inhibitors. Natalizumab, an $\alpha 4$ integrin inhibitor, is approved for use in CD. These drugs are reserved for patients nonresponsive to conventional therapies, including TNF inhibitors, and carry a risk of PML.

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Natalizumab is a monoclonal antibody against the alpha-4 subunit of integrin molecules. These molecules are important to adhesion and migration of cells from the vasculature into inflamed tissue. Natalizumab blocks integrin association with vascular receptors, limiting adhesion and transmigration of leukocytes. Efficacy in specific disorders may be related to reduction in specific inflammatory cell populations in target tissues. In multiple sclerosis, efficacy may be related to blockade of T-lymphocyte migration into the central nervous system; treatment results in a decreased frequency of relapse. In Crohn disease, natalizumab decreases inflammation by binding to alpha-4 integrin, blocking adhesion and migration of leukocytes in the gut.

TYSABRI was evaluated in multiple sclerosis in two randomized, double-blind, placebo-controlled trials. Both studies enrolled patients who experienced at least one clinical relapse during the prior year and had a Kurtzke Expanded Disability Status Scale (EDSS) score between 0 and 5.0. Median time on study drug was 120 weeks in each study. Study MS1 enrolled patients who had not received any interferon-beta or glatiramer acetate for at least the previous 6 months; approximately 94% had never been treated with these agents. Patients were randomized in a 2:1 ratio to receive TYSABRI 300 mg intravenous infusion (n=627) or placebo (n=315) every 4 weeks for up to 28 months (30 infusions). Study MS2 enrolled patients who had experienced one or more relapses while on treatment with AVONEX® (Interferon beta-1a) 30 mcg intramuscularly (IM) once weekly during the year prior to study entry. Patients were evenly randomized to receive TYSABRI 300 mg (n=589) or placebo (n=582) every 4 weeks for up to 28 months (30 infusions). All patients continued to receive AVONEX 30 mcg IM once weekly. The efficacy of TYSABRI alone was not compared with the efficacy of TYSABRI plus AVONEX. The primary endpoint at 2 years was time to onset of sustained increase in disability, defined as an increase of at least 1 point on the EDSS from baseline EDSS ≥ 1.0 that was sustained for 12 weeks, or at least a 1.5 point increase on the EDSS from baseline EDSS=0 that was sustained for 12 weeks. Time to onset of sustained increase in disability was longer in TYSABRI-treated patients than in placebo-treated patients in Studies MS1 (Figure 1) and MS2. The proportion of patients with increased disability and the annualized relapse rate were also lower in TYSABRI treated patients than in placebo-treated patients in Studies MS1 and MS2.

The safety and efficacy of TYSABRI in Crohn's Disease were evaluated in three randomized, double-blind, placebo controlled clinical trials in 1414 adult patients with moderately to severely active Crohn's disease (Crohn's Disease Activity Index [CDAI] ≥ 220 and ≤ 450). Concomitant inhibitors of TNF- α were not permitted. Concomitant stable doses of aminosalicylates, corticosteroids, and/or immunosuppressants (e.g., 6-mercaptopurine, azathioprine, or methotrexate) were permitted, and 89% of patients continued to receive at least one of these medications. Although permitted in the clinical trials, combination therapy with immunosuppressants is not recommended. Overall, approximately two-thirds of patients were not taking concomitant immunosuppressants, and approximately one-third of patients were taking neither concomitant immunosuppressants nor concomitant corticosteroids. Induction of clinical response (defined as ≥ 70 -point decrease in CDAI from baseline) was evaluated in two studies. In Study CD1, 896 patients were randomized 4:1 to receive three monthly infusions of either 300 mg TYSABRI or placebo. At Week 10, 56% of the 717 patients receiving TYSABRI were in response compared to 49% of the 179 patients receiving placebo (treatment effect: 7%; 95% confidence interval (CI): [-1%, 16%]; $p=0.067$). In a post hoc analysis of the subset of 653 patients with elevated baseline C-reactive protein (CRP), indicative of active inflammation, 57% of TYSABRI patients were in response compared to 45% of those receiving placebo (treatment effect: 12%; 95% CI: [3%, 22%]; nominal $p=0.01$). Proportion with Sustained Increase in Disability In the second induction trial, Study CD2, only patients with elevated serum C-reactive Protein (CRP) were studied. A total of 509 patients were randomized 1:1 to receive three monthly infusions of either 300 mg TYSABRI or placebo. In Study CD2, in contrast to Study CD1, clinical response and clinical remission (defined as CDAI score <150) were required to be met at both Weeks 8 and 12, rather than at a single time-point. In studies CD1 and CD2, for subgroups defined by prior use of, or by inadequate response to prior therapies (i.e., corticosteroids, immunosuppressants, and inhibitors of TNF- α), the treatment effect was generally similar to that seen in the whole study population. In the subgroup of patients that were taking neither concomitant immunosuppressants nor concomitant corticosteroids, the treatment effect was generally similar to that seen in the whole study population. Patients with inadequate response to inhibitors of TNF- α appeared to have lower clinical response and lower clinical remission in both the treatment and placebo groups. For patients in Study CD2 with an inadequate response to prior treatment with inhibitors of TNF- α , clinical response at both

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Weeks 8 and 12 was seen in 38% of those randomized to TYSABRI, and clinical remission at both Weeks 8 and 12 was seen in 17%. Maintenance therapy was evaluated in Study CD3. In this study, 331 patients from Study CD1 that had had a clinical response to TYSABRI at both Weeks 10 and 12 were re-randomized 1:1 to treatment with continuing monthly infusions of either 300 mg TYSABRI or placebo. Maintenance of response was assessed by the proportion of patients who did not lose clinical response at any study visit for an additional 6 and 12 months of treatment. For subgroups in study CD3 defined by prior use of, or by inadequate response to prior therapies (i.e., corticosteroids, immunosuppressants, and inhibitors of TNF- α), the treatment effect was generally similar to that seen in the whole study population. In the subgroup of patients that were taking neither concomitant immunosuppressants nor concomitant corticosteroids, the treatment effect was generally similar to that seen in the whole study population. Patients with inadequate response to inhibitors of TNF- α appeared to have lower maintenance of clinical response and lower maintenance of clinical remission in both the treatment and placebo groups. For patients in study CD3 with an inadequate response to prior treatment with inhibitors of TNF- α , maintenance of clinical response through Month 9 was seen in 52% of those randomized to TYSABRI, and maintenance of clinical remission through Month 9 was seen in 30%. Given the requirement to discontinue chronic steroids it is important to note that in the subgroup of patients (n=65) who were receiving corticosteroid medication at baseline, responded to TYSABRI in Study CD1, and were re-randomized to TYSABRI in Study CD3, approximately two thirds were able to discontinue steroids within 10 weeks of initiating a steroid taper.

Tysabri Touch Prescribing Program

TYSABRI is available only through a restricted program under a REMS called the TOUCH® Prescribing Program because of the risk of PML.

For prescribers and patients, the TOUCH® Prescribing Program has two components: MS TOUCH® (for patients with multiple sclerosis) and CD TOUCH® (for patients with Crohn's disease).

Selected requirements of the TOUCH® Prescribing Program include the following:

- Prescribers must be certified and comply with the following:
 - Review the TOUCH® Prescribing Program prescriber educational materials, including the full prescribing information.
 - Educate patients on the benefits and risks of treatment with TYSABRI, ensure that patients receive the Medication Guide, and encourage them to ask questions.
 - Review, complete, and sign the Patient-Prescriber Enrollment Form.
 - Evaluate patients three months after the first infusion, six months after the first infusion, every six months thereafter, and for at least six months after discontinuing TYSABRI.
 - Determine every six months whether patients should continue on treatment and, if so, authorize treatment for another six months.
 - Submit to Biogen the “TYSABRI Patient Status Report and Reauthorization Questionnaire” six months after initiating treatment and every six months thereafter.
 - Complete an “Initial Discontinuation Questionnaire” when TYSABRI is discontinued, and a “6-Month Discontinuation Questionnaire” following discontinuation of TYSABRI.
 - Report cases of PML, hospitalizations due to opportunistic infections, and deaths to Biogen at 1-800-456-2255 as soon as possible.
- Patients must be enrolled in the TOUCH® Prescribing Program, read the Medication Guide, understand the risks associated with TYSABRI, and complete and sign the Patient-Prescriber Enrollment Form.
- Pharmacies and infusion centers must be specially certified to dispense or infuse TYSABRI.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Tysabri (natalizumab) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Tysabri (natalizumab) include: patients who have or have had PML, patients who have had a hypersensitivity reaction to Tysabri.

OTHER SPECIAL CONSIDERATIONS:

Boxed Warning: Progressive multifocal leukoencephalopathy: Natalizumab increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability.

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CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J2323	injection, natalizumab, 1mg

AVAILABLE DOSAGE FORMS:

Tysabri CONC 300MG/15ML single-dose vial

REFERENCES

1. Lichtenstein, G. R., FACP. (n.d.). Management of Crohn's Disease in Adults. Retrieved July 13,2018, from <https://gi.org/guideline/management-of-crohns-disease-in-adults/>
2. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: disease-modifying therapies for adults with multiple sclerosis: report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. [published correction appears in Neurology. 2019;92(2):112]. Neurology. 2018;90(17):777-788. doi: 10.1212/WNL.0000000000005347. [PubMed 29686116].
3. Tysabri [package insert]: Cambridge, MA: Biogen Inc; December 2021
4. Terdiman JP, Gruss CB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute guideline on the use of thiopurines, methotrexate, and anti-TNF-α biologic drugs for the induction and maintenance of remission in inflammatory Crohn's disease. Gastroenterology. 2013 Dec;145(6):1459-63. doi: 10.1053/j.gastro.2013.10.047.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements Quantity FDA-Approved Uses Appendix Background Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q2 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file